Dealdoc

Licensing agreement for small-molecule TGR5 agonist program including backups

Bristol-Myers Squibb
Exelixis

Oct 11 2010
Licensing agreement for small-molecule TGR5 agonist program including backups

**Companies:**
- Bristol-Myers Squibb
- Exelixis

**Announcement date:**
Oct 11 2010

**Deal value, US$m:**
310.0 : sum of upfront and milestone payments

**Related contracts:**
Licensing agreement for small-molecule ROR antagonists

- **Details**
- **Financials**
- **Termsheet**
- **Press Release**
- **Filing Data**
- **Contract**

**Details**

**Announcement date:**
Oct 11 2010

**Start date:**
Oct 08 2010

**Industry sectors:**
- Bigpharma
- Bigbiotech
- Pharmaceutical

**Therapy areas:**
- Metabolic » Diabetes

**Technology types:**
- Small molecules
- Collaborative R&D

**Deal components:**
- Development
- Licensing

**Stages of development:**
- Preclinical
- Phase I

**Geographic focus:**
Worldwide

**Financials**

**Deal value, US$m:**
310.0 : sum of upfront and milestone payments

**Upfront, US$m:**
60.0 : upfront payment

**Milestones, US$m:**
250.0 : potential development and approval milestone payments

**n/d : combined sales performance milestones**

**Royalty rates, %:**

n/d : royalties on net sales of products from each of the TGR5 programs

**Termsheet**

Two new collaboration agreements with Bristol-Myers Squibb.

Exelixis will grant to Bristol-Myers Squibb an exclusive license to its small-molecule TGR5 agonist program including backups.

Bristol-Myers Squibb will make a combined initial payment of $60 million to Exelixis.

Exelixis will be eligible for potential development and approval milestone payments of up to $250 million on TGR5.

Exelixis will also be eligible for combined sales performance milestones, and royalties on net sales of products from each of the TGR5.

Bristol-Myers Squibb will receive an exclusive worldwide license to develop and commercialize small molecule TGR5 agonists.

Under the TGR5 agreement, Bristol-Myers Squibb will have sole responsibility for research, development, manufacturing, and commercialization.

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Press Release

Exelixis, Inc. (EXEL) Licenses Two Drug Programs To Bristol-Myers Squibb Company (BMY); Exelixis Nabs $60M Upfront, Potentially $505M

SOUTH SAN FRANCISCO, Calif., Oct 11, 2010 (BUSINESS WIRE) -- Exelixis, Inc. /quotes/comstock/15!exel/quotes/nls/exel (EXEL 4.51, +0.28, +6.62%) announced today that it has entered into two new collaboration agreements with Bristol-Myers Squibb Company /quotes/comstock/13!bmy/quotes/nls/bmy (BMY 27.40, +0.24, +0.88%) . Under the first agreement, Exelixis will grant to Bristol-Myers Squibb an exclusive license to its small-molecule TGR5 agonist program including backups. Under the second agreement, the companies will collaborate to discover, optimize, and characterize small-molecule ROR antagonists. The companies have also made minor amendments to their XL281 and liver X receptor (LXR) agreements. Finally, under the companies’ cancer collaboration agreement Exelixis has opted to exercise its right to opt out of further co-development of XL139 and will receive an accelerated milestone payment.

Under the terms of the new agreements, Bristol-Myers Squibb will make a combined initial payment of $60 million to Exelixis. Exelixis will be eligible for potential development and approval milestone payments of up to $250 million on TGR5 and $255 million on the ROR antagonists. Exelixis will also be eligible for combined sales performance milestones, and royalties on net sales of products from each of the TGR5 and ROR programs. Bristol-Myers Squibb will receive an exclusive worldwide license to develop and commercialize small molecule TGR5 agonists and ROR antagonists. Under the TGR5 agreement, Bristol-Myers Squibb will have sole responsibility for research, development, manufacturing, and commercialization. Under the ROR agreement, Bristol-Myers Squibb and Exelixis will collaborate on ROR antagonist programs up to a pre-clinical transition point and then Bristol-Myers Squibb will have sole responsibility for the further research, development, manufacture, and commercialization.

Exelixis is granting rights to the ROR program in exchange for Bristol-Myers Squibb waiving rights to receive a third Investigational New Drug (IND) candidate as agreed to under a collaboration signed in 2006 between the two companies in the area of oncology.

After Exelixis opts-out of further co-development of XL139, Bristol-Myers Squibb will receive an exclusive worldwide license to develop and commercialize, and will have sole responsibility for the further development, manufacture, and commercialization of the compound.

"We continue our strong relationship with Bristol-Myers Squibb and are excited for these collaborations to maximize the potential of these novel programs and bring benefits to patients with serious diseases,” said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. “These transactions leverage our discovery expertise with the development expertise of Bristol-Myers Squibb in inflammation and metabolic diseases, and provide important additional resources for us to continue our focus on our clinical stage development pipeline.”

TGR5 is a G-protein coupled bile acid receptor (GPCR) which is highly expressed in the gall bladder and intestine. Through TGR5, bile acids promote the secretion of glucagon-like peptide-1 (GLP-1), a hormone that affects multiple metabolic parameters including increased insulin secretion from the pancreas and lowering of blood glucose. Stimulating GLP-1 secretion by activation of TGR5 has the potential to be complementary to the use of dipeptidyl peptidase-4 (DPP4) inhibitors for the treatment of diabetes.

ROR is a member of the nuclear hormone receptor family that is expressed in multiple cell types including T-cells. ROR plays a prominent role in the development and activity of the TH17 subset of T-cells, which secrete IL-17 and are associated with a variety of inflammatory disorders. Small molecule antagonists of ROR inhibit production of these pro-inflammatory cytokines and have broad potential as novel anti-inflammatory compounds.

The TGR5 license agreement and the amendment to the cancer collaboration agreement signed in 2006 are subject to antitrust clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary regulatory approvals.

About Exelixis

Exelixis, Inc. is a development-stage biotechnology company dedicated to the discovery and development of novel small molecule therapeutics for the treatment of cancer and other serious diseases. The company is leveraging its biological expertise and integrated research and development capabilities to generate a pipeline of development compounds with significant therapeutic and commercial potential for the treatment of cancer and potentially other serious diseases. Currently, Exelixis’ broad product pipeline includes investigational compounds in phase 3, phase 2, and phase 1 clinical development. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, sanofi-aventis, GlaxoSmithKline, Genentech (a wholly owned member of the Roche Group), Boehringer Ingelheim, and Daiichi-Sankyo. For more information, please visit the company’s web site at http://www.exelixis.com.

Filing Data

Not available.

Contract

LICENSE AGREEMENT

© 2009-2023, Wildwood Ventures Ltd. All rights reserved.
THIS LICENSE AGREEMENT (the “Agreement”) is made and entered into as of October 8, 2010 (the “Execution Date”) by and between EXELIXIS, INC., a Delaware corporation having its principal place of business at 170 Harbor Way, P.O. Box 511, South San Francisco, California 94083-0511 (“Exelixis”), and BRISTOL-MYERS SQUIBB COMPANY, a Delaware corporation headquartered at 345 Park Avenue, New York, New York, 10154 (“BMS”). Exelixis and BMS are sometimes referred to herein individually as a “Party” and collectively as the “Parties”.

RECITALS

A. BMS is a multinational health care company that has expertise and capability in researching, developing and marketing human pharmaceuticals.

B. Exelixis is a drug discovery company that has expertise and proprietary technology relating to compounds that modulate the metabolic target known as TGR5.

C. BMS and Exelixis desire to establish an agreement to license such Exelixis technology and expertise for the discovery, lead optimization and characterization of small molecule compounds, and to provide for the development and commercialization of novel therapeutic and prophylactic products based on such compounds.

NOW, THEREFORE, the Parties agree as follows:

1. DEFINITIONS

Capitalized terms used in this Agreement (other than the headings of the Sections or Articles) have the following meanings set forth in this Article 1, or, if not listed in this Article 1, the meanings as designated in the text of this Agreement.

1.1 “Affiliate” means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of the definition in this Section 1.1, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means the actual power, either directly or indirectly through one (1) or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of at least fifty percent (50%) of the voting stock of such entity, by contract or otherwise.

1.2 “ANDA” means an Abbreviated New Drug Application submitted to the FDA in conformance with applicable laws and regulations, or the foreign equivalent of any such application in any other country.

1.3 “BMS Licensed Know-How” means all Information (other than Patents) that is Controlled by BMS and its Affiliates, including Information Controlled jointly with Exelixis, as of the Effective Date or during the term of the Agreement that: (a) relates to a Licensed Compound, a composition containing a Licensed Compound, a formulation containing a Licensed Compound, or the manufacture or use of a Licensed Compound; and (b) is [*] for Exelixis to exercise the rights licensed to it under the Agreement or to perform its obligations under the Agreement.

1.4 “BMS Licensed Patents” means all Patents Controlled by BMS and its Affiliates, including Patents Controlled jointly with Exelixis, as of the Effective Date or during the term of this Agreement that: (a) cover a Licensed Compound, a composition containing a Licensed Compound, a formulation containing a Licensed Compound, or the manufacture or use of a Licensed Compound; and (b) are [*] for Exelixis to exercise the rights licensed to it under the Agreement or to perform its obligations under the Agreement.

1.5 “BMS TGR5 Compound” means any Small Molecule Compound that: (a) is [*] or [*] under the [*] or [*] that [*]; (b) [*] and [*] TGR5 [*]; and (c) is [*] TGR5, based on the [*].

1.6 “Change of Control” means any transaction in which a Party: (a) sells, conveys or otherwise disposes of all or substantially all of its property or business; or (b)(i) merges, consolidates with, or is acquired by any other Person (other than a wholly-owned subsidiary of such Party); or (ii) effects any other transaction or series of transactions; in each case of clause (i) or (ii), such that the stockholders of such Party immediately prior thereto, in the aggregate, no longer own, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock of the surviving Person following the closing of such merger, consolidation, other transaction or series of transactions. As used in this Section 1.6, “Person” means any corporation, firm, partnership or other legal entity or individual person.

1.7 “Commercialize” means to promote, market, distribute, sell (and offer for sale or contract to sell) or provide product support for a Product, including by way of example: (a) detailing and other promotional activities in support of a Product; (b) advertising and public relations in support of a Product, including market research, development and distribution of selling, advertising and promotional materials, field literature, direct-to-consumer advertising campaigns, media/journal advertising, and exhibiting at seminars and conventions; (c) developing reimbursement programs and information and data specifically intended for national accounts, managed care organizations, governmental agencies (e.g., federal, state and local), and other group purchasing organizations, including pull-through activities; (d) co-promotion activities not included in the above; (e) conducting Medical Education Activities and journal advertising; and (f) [*]. For clarity, “Commercializing” and “Commercialization” have a correlative meaning.
1.8 “Controlled” means, with respect to any compound, material, Information or intellectual property right, that the Party owns or has a license to such compound, material, Information or intellectual property right and has the ability to grant to the other Party access, a license or a sublicense (as applicable) to such compound, material, Information or intellectual property right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such access, license or sublicense.

1.9 “Development” means, with respect to a Product, those activities, including clinical trials, supporting manufacturing activities and related regulatory activities, that are necessary or useful to: (a) obtain the approval by the applicable Regulatory Authorities of the Drug Approval Application with respect to such Product in the applicable regulatory jurisdiction, whether alone or for use together, or in combination, with another active agent or pharmaceutical product; (b) maintain such approvals. To avoid confusion, Development [*] have a correlative meaning.

1.10 “Diligent Efforts” means the carrying out of obligations or tasks in a sustained manner consistent with the commercially reasonable efforts a Party devotes to a product or a research, development or marketing project of similar market potential, profit potential or strategic value resulting from its own research efforts. Diligent Efforts requires that the Party: (a) [*], (b) [*], and (c) [*] with respect to such [*].

1.11 “Dollars” or “$” means the legal tender of the United States.

1.12 “Drug Approval Application” or “DAA” means: (a) in the United States, an NDA (or a supplemental NDA for following indications), and (b) in any other country or regulatory jurisdiction, an equivalent application for regulatory approval required before commercial sale or use of a Product (or with respect to a subsequent indication) in such country or regulatory jurisdiction.

1.13 “EMEA” means BMS’ European, Central and Eastern European, Middle Eastern and African commercial territory, consisting of the following countries and regions: Algeria, Andorra, Austria, Baltic States, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Liechtenstein, Luxembourg, Malta, Morocco, Netherlands, Norway, Poland, Portugal, Romania, Russia, Saudi Arabia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Tunisia, Turkey, U.K., Ukraine, Vatican City, Lebanon, Jordan, Syria, Kuwait, Bahrain, Oman, UAE and Qatar. The EMEA also includes: (a) the former Soviet Union and commonwealth of independent states such as Georgia, Armenia and central Asian republics; and (b) exports from France to English and French speaking African countries not separately identified in the list. For clarity, the specific list of countries and regions may change to align with any corresponding changes to BMS’ business structures.

1.14 “EU” means the European Union, as its membership may be altered from time to time, and any successor thereto. The member countries of the European Union as of the Execution Date are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

1.15 “Executive Officers” means: (a) in the case of Exelixis, the [*] of Exelixis; and (b) in the case of BMS, [*].

1.16 “Exelixis Licensed Know-How” means all Information (other than Patents) that is Controlled by Exelixis and its Affiliates, including Information Controlled jointly with BMS, as of the Effective Date or during the term of this Agreement that: (a) relates to a Licensed Compound, a composition containing a Licensed Compound, a formulation containing a Licensed Compound, or the manufacture or use of a Licensed Compound; and (b) is [*] for BMS to exercise the rights licensed to it under the Agreement or to perform its obligations under the Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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1.18 “Exelixis TGR5 Compound” means: (a) XL475; and (b) any Small Molecule Compound that is controlled by Exelixis as of the Effective Date or during the Term of the Agreement that: (i) [ ] TGR5 [ ]; (ii) are [ ] TGR5, based on the [ ]; and (iii) are disclosed in the Exelixis Licensed Patents listed on Exhibit 1.17.

1.19 “FDA” means the U.S. Food and Drug Administration, and any successor thereto.

1.20 “GAAP” means U.S. generally accepted accounting principles, consistently applied.

1.21 [ ] means, with respect to a particular Product in a country, [ ]: (a) [ ]; (b) is [ ] ([ ] or [ ]); and (c) is [ ] or [ ] a [ ].

1.22 “HSR Act” means the U.S. Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time, and the rules, regulations, guidance and requirements promulgated thereunder as may be in effect from time to time.

1.23 “IND” means an Investigational New Drug Application submitted to the FDA in conformance with applicable laws and regulations, or the foreign equivalent of any such application in any other country.

1.24 “Information” means information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including, preclinical data, clinical trial data, databases, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures. For clarity, Information does not include any Patents.

1.25 “Invention” means any and all inventions and improvements, whether or not patentable, that are conceived or reduced to practice or otherwise made by or on behalf of a Party (and/or its Affiliates) in the performance of its obligations, or the exercise of its rights, under this Agreement.

1.26 “Joint Invention” means any Invention invented, made or discovered jointly by or on behalf of the employee(s), contractor(s) or agent(s) of both Parties (and/or their Affiliates).

1.27 “Knowledge” means, with respect of a Party, the [ ] facts and information [ ], or any [ ] of, or [ ], [ ], [ ] execution of this Agreement. For purposes of this definition, [ ] means any person in the [ ] of a Party.

[ ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

1.28 “Launch” means, for each Product in each country, the first arm’s-length sale to a Third Party for use or consumption by the public of such Product in such country after Regulatory Approval of such Product in such country. A Launch shall not include any Product sold for use in clinical trials, for research or for other non-commercial uses, or that is supplied as part of a compassionate use or similar program.

1.29 “Licensed Compounds” means: (a) any Exelixis TGR5 Compounds; (b) any BMS TGR5 Compound; and (c) any [ ], or [ ] of [ ].

1.30 “Major European Countries” means France, Germany, Spain, Italy, and the United Kingdom.

1.31 “Major Territory” means each of the following territories: (a) [ ].

1.32 “Manufacturing” means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, inspection, receiving, holding and shipping of Licensed Compounds, Products, or any raw materials or packaging materials with respect thereto, or any intermediate of any of the foregoing, including process and cost optimization, process qualification and validation, commercial manufacture, stability and release testing, quality assurance and quality control. For clarity, “Manufacture” has a correlative meaning.

1.33 “Materials” means: (a) Licensed Compounds; and (b) [ ] materials, including but not limited to [ ], that are in Exelixis’ Control and that [ ].

1.34 “NDA” means a New Drug Application submitted to the FDA in conformance with applicable laws and regulations.

1.35 “Net Sales” means the amount invoiced or otherwise billed by BMS, or its Affiliate or sublicensee, for sales or other commercial disposition of a Product to a Third Party purchaser, less the following to the extent included in such billing or otherwise actually allowed or incurred with respect to such sales: (a) discounts, including cash, trade and quantity discounts, price reduction programs, retroactive price adjustments with respect to sales of a product, charge-back payments and rebates granted to managed health care organizations or to federal, state and local

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governments (or their respective agencies, purchasers and reimbursers) or to trade customers, including but not limited to, wholesalers and
chain and pharmacy buying groups; (b) credits or allowances actually granted upon rejections or returns of Products, including for recalls or
damaged goods; (c) freight, postage, shipping and insurance charges actually allowed or paid for delivery of Products, to the extent billed; (d)
customs duties, surcharges and other governmental charges incurred in connection with the exportation or importation of a Product; (e) bad
debts relating to sales of Products that are actually written off by BMS in accordance with GAAP during the applicable calculation period; (f)
costs due to the factoring of receivables; and (g) taxes, duties or other governmental charges levied on, absorbed or otherwise imposed on sale
of Products, including without limitation any fees payable under the Health Care Reform Act of 2010, value-added taxes, or other governmental
charges otherwise measured by the billing amount, when included in billing, as adjusted for rebates and refunds, but specifically excluding taxes
based on net income of the seller; provided that all of the foregoing deductions are calculated in accordance with GAAP.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities

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Notwithstanding the foregoing, if any Product is sold under a bundled or capitated arrangement with other BMS products, then, solely for the
purpose of calculating Net Sales under this Agreement, any discount on such Products sold under such an arrangement shall be [*] for the
applicable accounting period. In case of any dispute as to the applicable [*] under the preceding sentence, the determination of same shall be
calculated and certified by [*], whose decision shall be binding.

A sale of a Product is deemed to occur upon invoicing. [*].

For sake of clarity and avoidance of doubt, sales by BMS, its Affiliates or sublicensees of a Product to [*]. Any Products [*] considered in
determining Net Sales hereunder.

In the event a Product is sold as an end-user product consisting of a combination of active functional elements or as a combined product and/or
service, Net Sales allocable to the Product in each such country, for purposes of determining royalty payments on such Product, shall be
determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable
method of determining same that takes into account, on a country-by-country basis, variations in potency, the relative contribution of each active
agent, component or service, as the case may be, in the combination, and relative value to the end user of each active agent, component or
service, as the case may be. Notwithstanding the foregoing, the Parties agree that, for purposes of this paragraph, drug delivery vehicles,
adjuvants, and excipients shall not be deemed to be “active ingredients” or “active functional elements”.

1.36 “Patent” means all: (a) unexpired letters patent (including inventor’s certificates and utility models) which have not been held invalid or
unenforceable by a court or other applicable governmental authority of competent jurisdiction from which no appeal can be taken or has been
taken within the required time period (and which have not been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise,
or been abandoned in accordance with or as permitted by the terms of this Agreement or by mutual written agreement), including any
substitution, extension, registration, confirmation, reissue, re-examination, supplementary protection certificates, confirmation patents, patent of
additions, renewal or any like filing thereof; (b) pending applications for letters patent which have not been canceled, withdrawn from
consideration, finally determined to be unallowable by the applicable governmental authority or court for whatever reason (and from which no
appeal is or can be taken), and/or abandoned in accordance with or as permitted by the terms of this Agreement or by mutual written consent,
including any continuation, division or continuation-in-part thereof and any provisional or other priority applications; and (c) any international
counterparts, and counterparts in any country, to clauses (a) and (b) above.

1.37 “Phase I Clinical Trial” means a clinical trial of a Product on sufficient numbers of normal volunteers and/or patients that is designed to
establish that such Product is safe for its intended use, can be delivered in a dose(s) that is therapeutically useful, and to support its continued
testing in Phase II Clinical Trials.

1.38 “Phase IIb Clinical Trial” means a clinical trial of a Product on sufficient numbers of patients that is designed to provide a preliminary
determination of safety and efficacy of such Product in the target patient population over a range of doses and dose regimens.

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1.39 “Phase III Clinical Trial” means a clinical trial of a Product on sufficient numbers of patients that is designed to establish that such Product is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with such Product in the dosage range to be prescribed, and to support Regulatory Approval of such Product or label expansion of such Product.

1.40 “Phase IIb Clinical Trial” means a clinical trial of a Product, initiated before regulatory approval and is not required for same, but which may provide data that further defines how and where the drug should be used. A Phase IIb Clinical Trial may include epidemiological studies, modeling and pharmacoeconomic studies, and investigator-sponsored clinical trials that are approved by BMS and that otherwise fit the foregoing definition.

1.41 “Phase IV Clinical Trial” means a product support clinical trial of a Product commenced after receipt of Regulatory Approval in the country where such trial is conducted. A Phase IV Clinical Trial may include epidemiological studies, modeling and pharmacoeconomic studies, and investigator-sponsored clinical trials studying Product that are approved by BMS and that otherwise fit the foregoing definition.

1.42 “Product” means any therapeutic or prophylactic product (for use in animals or humans) that contains or comprises a Licensed Compound.

1.43 “Registrational Trial” means, with respect to a given Product, either: (a) a Phase III Clinical Trial with such Product; or (b) a Phase IIb Clinical Trial that, at the time of commencement, is expected to be the basis for initial Regulatory Approval of such Product.

1.44 “Regulatory Approval” means any and all approvals (including Drug Approval Applications, supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority, national, supra-national (e.g., the European Commission or the Council of the EU), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or sale of a Product in a regulatory jurisdiction.

1.45 “Regulatory Authority” means the applicable national (e.g., the FDA), supra-national (e.g., the European Commission or the Council of the EU), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity that, in each case, governs the approval of a Product in such applicable regulatory jurisdiction.

1.46 “Research” means the following activities: (a) identifying Small Molecule Compounds as [*] compounds that [*] and [*] TGR5 by [*]; (b) conducting a [*] program to [*] such [*] compounds to [*] that [*] and [*] TGR5 (including the conduct of [*] and [*] studies, and [*] studies); and (c) conducting [*] on [*] for [*] (including the conduct of [*] studies, and related [*] and [*] activities). To avoid confusion, Research does not include the conduct of Development.

1.47 [*] means any: (a) [*] of the Exelixis TGR5 Compounds that are specifically disclosed in the Exelixis Licensed Patents listed on Exhibit 1.7; and (b) [*] of a [*] described in the foregoing subsection (a).

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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1.48 “Small Molecule Compound” means a molecule that [*] or [*]. For clarity, [*], shall be considered Small Molecule Compounds.

1.49 “Sole Invention” means any Invention invented or discovered solely by or on behalf of a Party (or its Affiliate) and its employees, contractors and/or agents.

1.50 “Target Potency Threshold” means, with respect to a Small Compound Molecule, that such Small Compound Compound [*] and [*] the activity of TGR5 with a half maximal effective concentration (“EC50”) of less than or equal to [*] in either the [*] assays or the [*] assays.

1.51 “Target Specificity Threshold” means, with respect to a Small Compound Molecule, that such Small Compound Compound demonstrates, in a [*] or [*], [*] TGR5 [*]: (a) [*] of [*] including [*], and [*]; and (b) [*] [*] or [*] [*] and [*].

1.52 “Territory” means the world.

1.53 “TGR5” means: (a) the gene for the G protein-coupled bile acid receptor 1, otherwise known as TGR5 (or GPBAR1, BG37, GPCR19, GPR131, M-BAR, AND MGC40597), [*]; (b) the protein encoded by such gene; and (c) all [*] and [*] thereof.

1.54 “Third Party” means any entity other than: (a) Exelixis; (b) BMS; or (c) an Affiliate of either Party.

1.55 “United States” or “U.S.” means the United States of America, and its territories, districts and possessions.
1.56 “Valid Claim” means: (a) a claim in an issued Patent that has not: (i) expired or been canceled; (ii) been declared invalid by an unreversed and unappealable or unappealed (within any applicable allowable time) decision of a court or other appropriate body of competent jurisdiction; (iii) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (iv) been abandoned in accordance with or as permitted by the terms of this Agreement or by mutual written agreement of the Parties; or (b) a claim under an application for a Patent that has been pending [*], and, in any case, which has not been canceled, withdrawn from consideration, finally determined to be unallowable by the applicable governmental authority or court for whatever reason (and from which no appeal is or can be taken), or abandoned.

1.57 “XL475” means the Small Molecule Compound with Exelixis identifier EXEL-04614475, as disclosed to BMS in writing prior to the Execution Date.

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8 Additional Definitions

The following table identifies the location of definitions set forth in various Sections of the Agreement.

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2. TRANSFER OF TGR5 TECHNOLOGY

2.1 General. As soon as practicable following the Effective Date, and for [*] thereafter, Exelixis shall use Diligent Efforts to transfer to BMS, solely in accordance with Section 2.2, all items of Information or Materials that are in Exelixis’ possession and Control as of the Effective Date and that are [*] for BMS to research or pre-clinically develop Licensed Compounds ("TGR5 Technology"); provided that subsequent to such [*] period, Exelixis will use commercially reasonable efforts to transfer Information and Materials that are in Exelixis’ possession and Control and that are requested by BMS for purposes of making a regulatory filing or patent application. BMS may request such a transfer in writing pursuant to Section 2.2. Additionally, BMS may request that Exelixis provide a reasonable amount of on-site advice or support in connection with the foregoing transfer until [*], and BMS shall reimburse Exelixis for reasonable travel costs incurred.

2.2 Transfer of TGR5 Technology. Exelixis shall transfer to BMS, upon prior written approval by the Parties, reasonable quantities of Information and Materials included in the TGR5 Technology solely as described below.

(a) Ownership. Except as otherwise provided in the Agreement, all rights, title and interest in and to such Information or Materials being transferred shall remain with Exelixis. All such Information or Materials shall be considered the Confidential Information of Exelixis and shall be subject to Article 9 of the Agreement.

(b) Permitted Use. BMS shall use the Information or Materials solely for the purposes of exercising its rights, and performing its obligations, under the Agreement, subject to any additional limitations due to Exelixis’ obligations to Third Parties relating to such Information or Materials (with such limitations being set forth in the applicable Transfer Addendum) (the “Permitted Use”). BMS shall not transfer, deliver or disclose any of the Materials to any Third Party, other than its Affiliates or bona fide collaborators or third party contract service providers, without Exelixis’ prior written consent, except as otherwise stipulated in the Transfer Addendum. The Materials shall not be used in humans, except as otherwise contemplated by the Agreement. Any unused Materials supplied by Exelixis shall be returned to Exelixis or destroyed as agreed upon in writing by the Parties.

(c) Unauthorized Use. The Parties do not intend for BMS to use the Materials other than for the Permitted Use. If BMS or its Affiliates or other transferees use the Information or Materials outside of the Permitted Use, and any inventions, improvements, discoveries or data arise (or result) from such unauthorized use (such inventions, improvements, discoveries and data, and all intellectual property rights related thereto, collectively the “Unauthorized Inventions”), then: (i) BMS shall promptly and fully disclose all such Unauthorized Inventions to Exelixis in writing; (ii) BMS shall comply with the terms of any upstream license agreement between Exelixis and a Third Party with respect to such Unauthorized Use of Materials; and (iii) Exelixis may pursue all rights and remedies it may have under this Agreement, or at law or in equity, with respect to any breach of BMS’ obligation of Permitted Use (and creation of any Unauthorized Inventions).
3. RESEARCH, DEVELOPMENT, MANUFACTURING & COMMERCIALIZATION OF PRODUCTS

3.1 Research, Development, & Manufacturing of Products

(a) Scope & Diligence. BMS shall have sole control and responsibility for the Research, Development, Manufacture (including formulation) and Commercialization of all Products. BMS shall bear all costs and expenses associated with the Research, Development, Manufacture (including formulation) and Commercialization of all Products. BMS shall use Diligent Efforts to Develop each such Product in the Territory, and BMS shall use Diligent Efforts to Commercialize each Product in the Territory in which BMS maintains a commercial presence for each indication for which it receives Regulatory Approval; provided, however, that BMS may satisfy its diligence obligations by sublicensing the Development and Commercialization of a Product to a Third Party pursuant to the terms of this Agreement. Exelixis may notify BMS in writing if Exelixis in good faith believes that BMS is not meeting its diligence obligations set forth in this Section 3.1(a), and the Parties shall meet and discuss the matter in good faith. Exelixis may further request review of BMS’ records generated and maintained as required under Section 3.1(b) below.

(b) Records. Each Party shall maintain complete and accurate records of all Research, Development, Manufacturing and Commercialization conducted by it or on its behalf related to each Product, and all Information generated by it or on its behalf in connection with Development under
this Agreement with respect to each such Product; provided that in the case of Exelixis, such obligation shall be limited to those records that exist as of the Effective Date. Each Party shall maintain such records at least until the later of: (i) [ * ] after such records are created, or (ii) [ * ] after the Launch of the Product to which such records pertain; provided that the following records shall be maintained for a longer period, in accordance with each Party’s internal policies on record retention: (i) scientific notebooks and (ii) any other records that either Party reasonably requests be retained in order to ensure the preservation, prosecution, maintenance or enforcement of intellectual property rights. Such records shall be at a level of detail appropriate for patent and regulatory purposes. Each Party shall have the right to review and copy such records of the other Party at reasonable times to the extent necessary or useful for such reviewing Party to conduct its obligations or enforce its rights under this Agreement.

(c) Reports. Beginning [ * ] after the Effective Date, and every [ * ] thereafter during the term of the Agreement, BMS shall submit to Exelixis a written progress report summarizing the Research, Development, Manufacturing and Commercialization performed by or on behalf of BMS with respect to Products. If reasonably necessary or useful for Exelixis to exercise its rights under this Agreement, Exelixis may request that BMS provide more detailed information and data regarding such reports by BMS, and BMS shall promptly provide Exelixis with information and data as is reasonably related to such request, at Exelixis’ expense. All such reports shall be considered Confidential Information of BMS.

3.2 Standards of Conduct. BMS shall perform, or shall ensure that its Affiliates, sublicensees and Third Party contractors perform, all Research, Development, Manufacturing and Commercialization activities in a good scientific and ethical business manner and in compliance with applicable laws, rules and regulations.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

4. REGULATORY

4.1 Regulatory Lead Party. BMS shall have sole responsibility for (and bear all costs and expenses associated with) all regulatory activities regarding Products. BMS shall also have sole responsibility for (and bear all costs and expenses associated with) worldwide pharmacovigilance for such Product. BMS and its Affiliates shall have sole responsibility for all pricing and reimbursement approval proceedings relating to each Product in the Territory.

4.2 Ownership of Regulatory Dossier. BMS will own all regulatory filings for such Product in order to facilitate BMS’ interactions with Regulatory Authorities. BMS shall prepare and draft all filings (including any supplements or modifications thereto and including the preparation of any electronic submission of a Drug Approval Application) to Regulatory Authorities in each such country for such Product.

4.3 Recalls in the Territory. Any decision to initiate a recall or withdrawal of a Product in the Territory shall be made by BMS. In the event of any recall or withdrawal, BMS shall take any and all necessary action to implement such recall or withdrawal in accordance with applicable law, with assistance from Exelixis as reasonably requested by BMS. The costs of any such recall or withdrawal in the Territory shall be borne solely by BMS.

5. MANUFACTURING

5.1 Transfer of Manufacturing Information.

(a) Promptly following the Effective Date, Exelixis shall transfer the Manufacturing technology Controlled by Exelixis for XL475 to BMS. As soon as is practicable after its receipt of such request, Exelixis shall transfer to BMS all Information that is Controlled by Exelixis, that is related to the Manufacturing of Licensed Compounds, and that is [ * ] to enable BMS to Manufacture Licensed Compounds.

(b) BMS shall use any Information transferred pursuant to Section 5.1(a) solely for the purpose of Manufacturing Licensed Compounds and/or Products for use by BMS under this Agreement, and for no other purpose.

6. LICENSES; INTELLECTUAL PROPERTY

6.1 Licenses to BMS. Subject to the terms of this Agreement:

(a) Research. Exelixis hereby grants to BMS an exclusive, worldwide, royalty-free license (without the right to sublicense except to third party contract research providers and manufacturers) under the Exelixis Licensed Know-How and the Exelixis Licensed Patents to research, identify, derivatize, pre-clinically develop, make, have made, and use Licensed Compounds solely for research purposes.
(b) Clinical Development and Commercialization. Exelixis hereby grants to BMS an exclusive, worldwide, royalty-bearing license (with the right to sublicense) under the Exelixis Licensed Know-How and Exelixis Licensed Patents to clinically develop, make, have made, use, import, sell, offer to sell and have sold Products incorporating any Licensed Compound.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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(c) Exelixis Retained Rights. Exelixis retains all rights to use the Exelixis Licensed Know-How and Exelixis Licensed Patents except those expressly granted to BMS on an exclusive basis under the terms of this Agreement. In addition, notwithstanding the exclusive licenses granted to BMS pursuant to Section 6.1, Exelixis retains the right under the Exelixis Licensed Patents and the Exelixis Licensed Know-How to make, have made, use, and test Exelixis TGR5 Compounds solely for internal research purposes.

6.2 BMS Covenants. BMS hereby covenants that BMS shall not (and shall ensure that any of its permitted sublicensees shall not) use any Exelixis Licensed Know-How or Exelixis Licensed Patents for a purpose other than that expressly permitted in Section 6.1.

6.3 No Additional Licenses. Except as expressly provided in Sections 6.1, 6.2, and Article 10, nothing in this Agreement grants either Party any right, title or interest in and to the intellectual property rights of the other Party (either expressly or by implication or estoppel). For clarity, the licenses granted in Sections 6.1 by Exelixis to BMS does not give BMS any right or license to incorporate into any Product (e.g., as a combination product) any compound that is Controlled by Exelixis and that is not a Licensed Compound. For clarity, the licenses granted in Section 10.5 by BMS to Exelixis do not give Exelixis any right or license to incorporate into any Product (e.g., as a combination product) any compound that is Controlled by BMS and that is not a Licensed Compound.

6.4 Sublicensing. The license granted to BMS in Section 6.1(b) shall be freely sublicenseable by BMS in connection with the Development, Commercialization and/or Manufacturing of Products. BMS shall provide Exelixis with the name of each permitted sublicensee of its rights under this Article 6 and a copy of the applicable sublicense agreement; provided that BMS may redact confidential or proprietary terms from such copy, including financial terms. BMS shall remain responsible for each permitted sublicensee's compliance with the applicable terms and conditions of this Agreement. Each sublicense granted by BMS under this Article 6 to a party that is an Affiliate of BMS at the time such license is granted shall terminate immediately upon such party ceasing to be an Affiliate of BMS.

6.5 Ownership.

(a) The inventorship of all Inventions shall be determined under the U.S. patent laws.

(b) Each Party shall own the entire right, title and interest in and to any and all of its Sole Inventions, and Patents claiming only such Sole Inventions (and no Joint Inventions) (“Sole Invention Patents”). BMS and Exelixis shall be joint owners in and to any and all Joint Inventions and Patents claiming such Joint Inventions (“Joint Invention Patents”). Subject to Section 6.1, BMS and Exelixis as joint owners each shall have the right to exploit and to grant licenses under such Joint Inventions, and where exercise of such rights require, under the laws of a country, the consent of the other Party, with the consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned) unless otherwise specified in this Agreement (including where such rights are exclusively licensed to the other Party hereunder).

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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(c) All employees, agents and contractors of each Party shall be under written obligation to assign any inventions and related intellectual property to the Party for whom they are employed or are providing services.

(d) The Parties acknowledge and agree that this Agreement shall be deemed to be a “Joint Research Agreement” as defined under 35 U.S.C. 103(c).

6.6 Disclosure. Each Party shall submit a written report to the other Party no less frequently than within [*] of the end of each [*] describing any Sole Invention or Joint Invention arising during the prior [*] in the course of the Agreement which it believes may be patentable or at such earlier time as may be necessary to preserve patentability of such invention. Each Party shall provide to the other Party such assistance and execute such documents as are reasonably necessary to permit the filing and prosecution of such patent application to be filed on any such Sole Invention or Joint Invention, or the issuance, maintenance or extension of any resulting Patent.
6.7 Patent Prosecution and Maintenance; Abandonment.

(a) Joint Patent Committee.

(i) Establishment & Meetings. Promptly after the Effective Date, the Parties shall establish a committee (the “Joint Patent Committee” or “JPC”). The JPC shall be composed of at least (1) representative from each Party, at least one of which shall be a patent counsel for such Party. Each Party may change its representative(s) by giving the other Party at least [*] prior written notice. The JPC shall meet within [*] after the Effective Date, and once per [*] thereafter, or as may be requested by either Party as necessary, by teleconference, videoconference or in person (as determined by the JPC).

(1) Duties. Promptly after the Effective Date, [*] shall oversee (subject to Sections 6.7(a)(iii), (iv) and (v) below) the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all [*] Patents, [*] Patents Controlled by [*], and [*] Patents that in each case are [*] (the [*] Patents), provided that, unless otherwise agreed by the Parties, such responsibilities shall be carried out by: (A) [*] by [*] the [*], unless there exists [*] and [*]; (B) [*] by [*], but only in the case where [*] described in subsection (A) had [*] of [*]; or (C) [*] in conjunction with [*] described in the preceding subsection (A) or (B), as applicable. [*] or [*], shall provide [*] with an update of the filing, prosecution and maintenance status for each of the [*] Patents on a periodic basis, and shall use commercially reasonable efforts to consult with and cooperate with [*] with respect to the filing, prosecution and maintenance of the [*] Patents, including providing [*] with drafts of proposed filings to allow [*] a reasonable opportunity for review and comment before such filings are due. [*], or [*], shall provide to [*] copies of any papers relating to the filing, prosecution and maintenance of the [*] Patents promptly upon their being filed and received.

(2) Decisions. Subsequent to the Effective Date, in the event of a dispute between the Parties with regard to the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of any [*] Patent, the matter shall be promptly referred to the [*] of Exelixis and [*] for BMS. If these two (2) individuals are unable to resolve the dispute promptly, then the matter shall be promptly elevated to [*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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the [*] of Exelixis and the [*] of BMS. If these two (2) individuals are unable to resolve the dispute promptly, then, subject to Sections 6.7(a)(i)(3), 6.7(a)(i)(4), 6.7(a)(ii), [*] of the ROR Collaboration Agreement, and [*] of the ROR Collaboration Agreement, [*] shall have the final decision, except if such decision: (A) conflicts with the terms of the Agreement; (B) would result in [*] described in [*] or a [*] of the [*]; or (C) materially impacts [*] prosecution of Patents that [*] in, in which case of subsection 6.7(a)(i)(2)(A) - (C), [*] shall have the final decision.

(3) Limitation on Subsection 6.7(a)(i)(2)(B). If [*] reasonably believes that filing a new patent application covering a [*] (other than the [*] of a [*] would result in potential claims [*] for [*], and if [*] disputes with [*] that such patent application should be filed, then such dispute shall be discussed as described in the first two (2) sentences of Section 6.7(a)(ii)(2), and, if still unresolved, shall be arbitrated pursuant to Section [*] of the ROR Collaboration Agreement, and [*] not have the right to exercise its final-decision making authority pursuant to Subsection 6.7(a)(i)(2)(B) unless the dispute is resolved in [*] favor.

(4) Limitation on Subsection 6.7(a)(i)(2)(C). [*] hereby covenants that it shall not, without the prior written consent of [*] (which shall not be unreasonably delayed or conditioned), during the term of this Agreement, [*] the decision-making authority granted to [*] pursuant to Subsection 6.7(a)(i)(2)(C) [*] that is [*] as of the Effective Date or [*]. Furthermore, if [*] the decision-making authority granted to [*] pursuant to Subsection 6.7(a)(i)(2)(C) [*] by [*] or [*], and such [*] is [*] a [*] that is [*], then [*] and [*] shall agree, pursuant to Section [*] of the ROR Collaboration Agreement, on [*] the decision-making authority granted to [*] pursuant to Subsection 6.7(a)(i)(2)(C).

(ii) Abandonment. In no event shall [*] knowingly permit any of the [*] Patents to be abandoned in any country, or elect not to file a new patent application claiming priority to a patent application within the [*] Patents either before such patent application’s issuance or within the time period required for the filing of an international (i.e., Patent Cooperation Treaty), regional (including European Patent Office) or national application, without [*] written consent (such consent not to be unreasonably withheld, delayed or conditioned) or [*] otherwise first being given an opportunity to assume full responsibility (at [*] expense) for the continued prosecution and maintenance of such [*] Patents or the filing of such new patent application. Accordingly, [*], or [*], shall provide [*] with notice of the allowance and expected issuance date of any patent within the [*] Patents, or any of the aforementioned filing deadlines, and [*] shall provide [*] with prompt notice as to whether [*] desires [*] to file such new patent application. In the event that [*] decides either: (A) not to continue the prosecution or maintenance of a patent application or patent within the [*] Patents in any country; or (B) not to file such new patent application requested to be filed by [*], [*] shall provide [*] with notice of this decision at least [*] prior to any pending lapse or abandonment thereof, and [*] shall thereafter have the right to assume responsibility for the filing, prosecution and maintenance of such patent or patent application. In the event that [*] assumes such responsibility for such filing, prosecution and maintenance, [*] shall no longer have the responsibility for such filing, prosecution and
maintenance of such patent applications and patents, and [*] shall cooperate as reasonably requested by [*] to facilitate control of such filing, prosecution and maintenance by [*]. In the case where [*] takes over the filing, prosecution or maintenance of any patent or patent application as set forth above, such patent or patent application shall [*] be [*] the [*], and [*] shall [*] such patent or patent application.

(iii) Filing, Prosecution and Maintenance of Sole Invention Patents Controlled by BMS. In accordance with this Section 6.7(a)(iii), BMS shall be responsible for the filing, prosecution (including any interferences, reissues and reexaminations) and maintenance of all Sole Invention Patents Controlled by BMS. BMS shall provide to Exelixis copies of any papers relating to the filing, prosecution and maintenance of the Sole Invention Patents Controlled by BMS promptly upon their being filed and received.

(iv) Patent Term Extension. Exelixis and BMS shall each cooperate with each another and shall use commercially reasonable efforts in obtaining patent term extension (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to patent rights covering the Products. If elections with respect to obtaining such patent term extensions are to be made, [*] shall have the right to make the election to seek patent term extension or supplemental protection.

(v) Exelixis Right to Separate Claims. To the extent that any Sole Invention Patent of Exelixis contains claims that cover compounds that are not Licensed Compounds (such compounds, “Separable Compounds”), Exelixis shall have the right to separate any claims that cover such Separable Compounds (and not Licensed Compounds) and to file such claims in a separate application (e.g., a continuation, continuation-in-part, or divisional application). Exelixis shall notify BMS in writing prior to separating such claims, and such separation shall be at Exelixis’ sole expense.

(b) Payment of Prosecution Costs. [*] shall bear the out-of-pocket expenses (including reasonable fees for any outside counsel, [*]) associated with the filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of: (X) Patents covering [*]; and (Y) the [*] Patents, provided that if any [*] or [*] is part of a patent application or patent that [*] that are [*], then the Parties shall mutually agree upon an appropriate allocation of the expenses so that [*] does not bear any portion of the out-of-pocket expenses attributable to [*].

(c) Payment of Expenses for Joint Inventions. Exelixis and BMS shall mutually agree on the percentage of expenses that each Party shall bear with respect to Joint Inventions for which the cost of filing, prosecuting or maintaining such Joint Invention is not the responsibility of a Party under Section 6.7(b) hereof (which, in the absence of any other agreement between the Parties, shall be divided evenly).

(d) Non-payment of Expenses.

(i) If a Party elects not to pay its share of any expenses with respect to a Patent covering a [*] in a given country under any of Sections [*] (each, a [*] Patent), such Party shall inform the other Party in writing not less than [*] before any relevant deadline (or, in the event of a shorter period in which to respond to a patent office, as soon as reasonably practicable), and, if the other Party assumes the expenses associated with the [*] Patent, then the assuming Party shall thereby become the sole owner of such [*] Patent in such country and the other Party shall assign to the assuming Party its rights, title and interests in such [*] Patent in such country.

(ii) If a Party is the assignee or owner of a Patent (other than a [*] Patent) that is licensed to the other Party under Section 6.1, and such owning Party elects not to pay its share of expenses pursuant to Sections [*] in a given country, such owning Party shall inform the other Party in writing not less than [*] before any relevant deadline (or, in the event of a shorter period in which to respond to a patent office, as soon as reasonably practicable). If the other Party assumes the expenses associated with the Patent in such country, then the assuming Party shall thereby [*] such Patent and the owning Party shall [*] such Patent in such country.

(iii) If a Party is the licensee of a Patent (other than a [*] Patent) under any of Sections 6.1 or 6.2, and such Party elects not to pay its share of expenses pursuant to Sections [*] in a given country, such Party shall inform the other Party in writing not less than [*] before any relevant
6.8 Enforcement of Patent Rights.

(a) Enforcement of Exelixis Sole Patents.

(i) Enforcement by [*]. In the event that management or in-house counsel for either Party becomes aware of a suspected infringement by a Third Party of a Patent claiming a Sole Invention of Exelixis that claims the composition of matter (including formulation), manufacture or use of one or more Licensed Compound(s) or Product(s) that is being Developed or Commercialized by BMS or its Affiliate or sublicensee using Diligent Efforts and which is exclusively licensed to BMS under Section 6.1 (for purposes of this Section 6.8(a)(i) only, an “Exelixis Sole Patent”), such Party shall notify the other Party promptly, and following such notification, the Parties shall confer. Each Party shall provide the same level of disclosure to the other Party’s in-house counsel concerning suspected infringement of an Exelixis Sole Patent as such

(ii) Enforcement by [*]. If [*] elects not to bring any action for infringement or to defend any proceeding described in Section 6.8(a)(i) and so notifies [*], or where [*] otherwise desires to bring an action or to defend any proceeding directly involving an Exelixis Sole Patent, then [*] may bring such action or defend such proceeding at its own expense, in its own name and entirely under its own direction and control; [*] shall reasonably assist [*] in such actions or proceedings if so requested, and shall lend its name to such actions or proceedings if requested by [*] or required by law, and [*] shall hold [*] harmless from any liability incurred by [*] arising out of any such proceedings or actions at [*] request; [*] shall have the right to participate and be represented in any such suit by its own counsel at its own expense. No settlement of any such action or defense which restricts the scope, or adversely affects the enforceability, of any such Exelixis Sole Patent that is a Patent [*] (or foreign equivalent(s) of such Patent or the [*]) by [*] (a “[*] Patent”), if [*] fails to consent to any such action or proceeding, the [*] for any [*] such Exelixis Sole Patent shall in no event [*] by any failure to enforce such Exelixis Sole Patent. [*] shall reasonably assist [*] in such actions or proceedings if so requested by [*] or required by law, and [*] shall hold [*] harmless from any liability incurred by [*] arising out of any such proceedings or actions. [*] shall have the right to participate and be represented in any such suit by its own counsel at its own expense. No settlement of any such action or defense which restricts the scope, or adversely affects the enforceability, of any such Exelixis Sole Patent may be entered into by [*] without the prior consent of [*] (such consent not to be unreasonably withheld, delayed or conditioned).

(b) Enforcement of Joint Patents.

(i) Joint Product Patents.

(1) Enforcement by [*]. In the event that management or in-house counsel for either Party becomes aware of a suspected infringement of a Patent claiming a Joint Invention that pertains to the composition of matter (including formulation), manufacture or use of one or more Licensed Compound(s) or Product(s) that is being Developed or Commercialized by BMS or its Affiliate or sublicensee using Diligent Efforts and (a “Joint Product Patent”), such Party shall notify the other Party promptly, and following such notification, the Parties shall confer. Each Party shall provide the same level of disclosure to the other Party’s in-house counsel concerning suspected infringement of a Joint Product Patent as such
to defend such proceedings at its own expense, in its own name and entirely under its own direction and control. [*] shall reasonably assist [*]
(at [*] expense) in such actions or proceedings if so requested, and shall lend its name to such actions or proceedings if requested by [*]
or required by law, and [*] shall hold [*] harmless from any liability incurred by [*] arising out of any such proceedings or actions. [*] shall have
the right to participate and be represented in any such suit by its own counsel at its own expense. No settlement of any such action or defense
which restricts the scope or affects the enforceability of a Joint Product Patent may be entered into by [*] without the prior consent of [*]
(such consent not to be unreasonably withheld, delayed or conditioned).

(2) Enforcement by [*]. If [*] elects not to bring any action for infringement or to defend any proceeding described in Section 6.8(b)(i)(1) and so
notifies [*], or for any other enforcement by [*] of a Joint Product Patent which is exclusively licensed to BMS under Section 6.1, then [*] may
bring such action or defend such proceeding at its own expense, in its own name and entirely under its own direction and control; provided that
[*] must confer with [*] with respect to any such action or proceeding and obtain the prior written consent of [*] to commence such action or
proceeding, such consent not to be unreasonably withheld, delayed or conditioned; provided further, that with respect to any Joint Product
Patent that is a [*] Patent, if [*] fails to consent to any such action or proceeding, the [*] for any [*] such Joint Product Patent shall in no
event [*] by any failure to enforce such Joint Product Patent. [*] shall reasonably assist [*] (at [*] expense) in any action or proceeding being
prosecuted or defended by [*], if so requested by [*] or required by law, and [*] shall hold [*] harmless from any liability incurred by [*]
arising out of any such proceedings or actions. [*] shall have the right to participate and be represented in any such suit by its own counsel at
its own expense. No settlement of any such action or defense which restricts the scope or affects the enforceability of a Joint Product Patent
may be entered into by [*] without the prior consent of [*] (such consent not to be unreasonably withheld, delayed or conditioned).

(ii) Other Joint Patents.

(1) Enforcement by [*]. In the event that management or in-house counsel for either Party becomes aware of a suspected infringement of a
Patent that claims a Joint Invention but is not a Joint Product Patent (an “Other Joint Patent”), such Party shall notify the other Party promptly,
and following such notification, the Parties shall confer. Each Party shall provide the same level of disclosure to the other Party’s in-house
counsel concerning suspected infringement of an Other Joint Patent as such Party would provide with respect to suspected infringement of its
own issued Patent or an exclusively licensed issued Patent claiming a product it is developing or commercializing independent of this
Agreement. [*] shall have the right, but shall not be obligated, to prosecute an infringement action or to defend such proceedings at its own
expense, in its own name and entirely under its own direction and control. [*] shall reasonably assist [*] (at [*] expense) in such actions or
proceedings if so requested, and shall lend its name to such actions or proceedings if requested by [*] or required by law, and [*] shall hold [*]
harmless from any liability incurred by [*] arising out of any such proceedings or actions. [*] shall have the right to participate and be
represented in any such suit by its own counsel at its own expense. No settlement of any such action or defense which restricts the scope or
affects the enforceability of an Other Joint Patent may be entered into by [*] without the prior consent of [*] (such consent not to be
unreasonably withheld, delayed or conditioned).

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities

(2) Enforcement by [*]. If [*] elects not to bring any action for infringement or to defend any proceeding described in Section 6.8(b)(ii)(1) and so
notifies [*], then [*] may bring such action or defend such proceeding at its own expense, in its own name and entirely under its own direction
and control; provided that [*] must confer with [*] with respect to any such action or proceeding and obtain the prior written consent of [*]
to commence such action or proceeding, such consent not to be unreasonably withheld, delayed or conditioned; provided further, that with respect
to any Other Joint Patent that is a [*] Patent, if [*] fails to consent to any such action or proceeding, the [*] for any [*] such Other Joint Patent
shall in no event [*] by any failure to enforce such Other Joint Patent. [*] shall reasonably assist [*] (at [*] expense) in any action or
proceeding being prosecuted or defended by [*], if so requested by [*] or required by law, and [*] shall hold [*] harmless from any liability
incurred by [*] arising out of any such proceedings or actions. [*] shall have the right to participate and be represented in any such suit by its
own counsel at its own expense. No settlement of any such action or defense which restricts the scope or affects the enforceability of an Other

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Joint Patent may be entered into by [*] without the prior consent of [*] (such consent not to be unreasonably withheld, delayed or conditioned).

(c) General Provisions Relating to Enforcement of Patents.

(i) Withdrawal. If either Party brings such an action or defends such a proceeding under this Section 6.8 and subsequently ceases to pursue or withdraws from such action or proceeding, it shall promptly notify the other Party and the other Party may substitute itself for the withdrawing Party under the terms of this Section 6.8 (including such prior written consent as provided for under this Section 6.8) at its own expense.

(ii) Recoveries. In the event either Party exercises the rights conferred in this Section 6.8 and recovers any damages or other sums in such action, suit or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith, including attorneys fees. If such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be shared in proportion to the total such costs and expenses incurred by each Party. If after such reimbursement any funds shall remain from such damages or other sums recovered, such funds shall be [*].

(d) Data Exclusivity and Orange Book Listings. With respect to data exclusivity periods (such as those periods listed in the FDA’s Orange Book (including any available pediatric extensions) or periods under national implementations of Article 9.1(a)(iii) of Directive 2001/EC/83, and all international equivalents), BMS shall use commercially reasonable efforts consistent with its obligations under applicable law (including any applicable consent order) to seek, maintain and enforce all such data exclusivity periods available for the Products. With respect to filings in the FDA Orange Book (and foreign equivalents) for issued patents for a Product, upon request by BMS (and at BMS’ expense), Exelixis shall provide reasonable cooperation to BMS in filing and maintaining such Orange Book (and foreign equivalent) listings.

(e) No Action in Violation of Law. Neither Party shall be required to take any action pursuant to this Section 6.8 that such Party reasonably determines in its sole judgment and discretion conflicts with or violates any court or government order or decree applicable to such Party.

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6.9 Defense of Third Party Claims. If a claim is brought by a Third Party that any activity related to work performed by a Party under the Agreement infringes the intellectual property rights of such Third Party, each Party shall give prompt written notice to the other Party of such claim, and following such notice, the Parties shall confer on how to respond.

6.10 Copyright Registrations. Copyrights and copyright registrations on copyrightable subject matter shall be filed, prosecuted, defended, and maintained, and the Parties shall have the right to pursue infringers of any copyrights owned or Controlled by it, in substantially the same manner as the Parties have allocated such responsibilities, and the expenses thereof, for patent rights under this Article 6.

7. COMPENSATION

7.1 Upfront Payment. BMS shall pay Exelixis an upfront payment of Thirty-Five Million Dollars ($35,000,000) within [*] after the Effective Date. Such payment shall be noncreditable and nonrefundable.

7.2 Milestone Payments to Exelixis.

(a) Development and Regulatory Milestones. For each Product, BMS shall make the milestone payments set forth below to Exelixis within [*] after the first achievement of each indicated event by BMS or any of its Affiliates or sublicensees with respect to such Product. All such milestone payments made by BMS to Exelixis hereunder shall be noncreditable and nonrefundable. For clarity, with respect to milestones that are triggered by the [*], such [*] must be [*] that is [*] and [*] the [*] or [*] the [*]. For example, if the [*] is [*] the [*] or [*], a milestone for [*] would be possible for the first occurrence of [*] that is [*] and [*] the [*] or [*] (such as [*], etc).
Event

Milestone

Payment

(i) $  

(ii) $  

(iii) $  

(iv) $  

(v) $  

(vi) $  

(vii) $  

(viii) $  

(ix) $  

(x) $  

(xii) $  

(b) Commercial Milestones. BMS shall make the milestone payments set forth below to Exelixis after first achievement of each indicated event by BMS or any of its Affiliates or sublicensees with respect to each Product. Each milestone payment shall be made by BMS $ after the end of the in which such milestone event is met. BMS shall pay to Exelixis if, at the time, the the payment obligation (the [ ]) was for the [ ]. Otherwise, the shall be [ ], provided that [ ]. BMS shall pay to Exelixis if, at the time [ ], the [ ] for the [ ]. Otherwise, the shall be [ ], provided that the [ ]. All such milestone payments made by BMS to Exelixis

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hereunder shall be noncreditable and nonrefundable, and shall be paid only once with respect to each Product.

Event

Milestone Payment

[*]

$[*]

[*]

$[*]

[*]

$[*]

(c) Milestone Payment Restrictions. Each milestone payment set forth in Section 7.2(a) shall be paid [*] with respect to [*], [*] the [*] or [*] the [*] in [*] for [*], or the [*] or [*] for [*].

(d) Milestone Payments for [*]. If BMS is diligently developing and paying milestones to Exelixis under Section 7.2(a) [*], the payments otherwise to be made to Exelixis under Sections 7.2(a) for [*] shall be [*] such [*] the [*] in [*], in which case BMS shall pay Exelixis [*] any such [*] in [*] within [*] of the [*] such [*]; provided, however, that if this Agreement terminates before such [*], then BMS shall [*] pay Exelixis the [*]. If [*] the [*]

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7.3 Royalty Payments to Exelixis for Net Sales of Products. For each Product, and for all Program Backups that are Products, BMS shall pay to Exelixis royalties on Net Sales of such Product by BMS (or its Affiliates or sublicensees) in the Territory at a royalty rate determined by aggregate Net Sales in the Territory of such Product in a calendar year as follows:

Calendar year Net Sales of Products in the Territory

Royalty Rate

First $[*]

[*]%

Portion above $[*] and up to and including $[*]

[*]%

Portion above $[*]

[*]%

For clarity, Net Sales shall be [*]. For the purpose of this Section 7.3, all Products [*] shall be [*] and the Net Sales of such Products shall be [*] the [*], regardless of whether [*] or [*], or [*] or [*]. All royalty payments made by BMS to Exelixis hereunder shall be noncreditable and nonrefundable, [*] to Exelixis, in which case such [*] shall be [*] (or, in the event that [*], such [*] shall be [*]).

7.4 Third Party Royalties for Products in the Territory and Products in the U.S.

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(a) [*] all Third Party royalties owed with respect to either a Product in the Territory on intellectual property that is intellectual property that: (A) [*] from a Third Party prior to the Effective Date and [*]; and (B) [*]. Subject to Section 7.4(b), [*] Third Party royalties owed on intellectual property in connection with the development and commercialization of a Product in the Territory; provided that each Party shall bear all Third Party royalties arising from any infringing activities by such Party prior to the Effective Date.

(b) BMS may deduct from the royalties it would otherwise owe to Exelixis pursuant to Section 7.3 for a particular Product, an amount equal to [*] of all royalties payable to a Third Party in consideration for rights necessary or reasonably useful for the manufacture, use or sale of such Product, up to a maximum deduction of [*] of the royalties due Exelixis for such Product.

7.5 [*]. During the applicable Royalty Term for a particular Product, if the Patents claiming the composition of matter of such Product have expired, and if any [*]: (a) [*] in any given country in any year; and (b) such [*] in such country for such year are, [*]:

(i) [*], but [*] of the [*] in such country, then [*]; or

(ii) [*] of the [*] in such country, then [*].

7.6 Limitation on Deductions. Notwithstanding anything to the contrary in this Agreement, the operation of Section 7.4 and Section 7.5 for a given Product, whether singularly or in combination with each other, shall not [*].

7.7 Quarterly Payments and Reports. All royalties due under Section 7.3 shall be paid quarterly, on a country-by-country basis, within [*] of the end of the relevant quarter for which royalties are due. BMS shall provide to Exelixis within [*] after the end of each quarter a report that summarizes the Net Sales of a Product during such quarter, provided that to the extent additional information is reasonably required by Exelixis to comply with its obligations to any of its licensors, the Parties shall work together in good faith to timely compile and produce such additional information. Such reports shall also include detailed information regarding the calculation of royalties due pursuant to Section 7.3, including allowable deductions in the calculation of Net Sales of each Product on which royalties are paid, and, to the extent Section 7.5 is applicable, the calculation of [*] and [*] of [*].

7.8 Term of Royalties. Exelixis’ right to receive royalties under Section 7.3 shall expire on a country-by-country and Product-by-Product basis upon the later of: (a) [*]; or (b) [*] (the “Royalty Term”). Upon the expiration of the Royalty Term with respect to a Product in a country, BMS shall have a fully-paid-up perpetual license under Sections 6.1(a) and 6.1(b) for the making, using, selling, offering for sale and importing of such Product in such country.

7.9 Payment Method. All payments due under this Agreement to Exelixis shall be made by bank wire transfer in immediately available funds to an account designated by Exelixis. All payments hereunder shall be made in Dollars.

7.10 Taxes. Exelixis shall pay any and all taxes levied on account of all payments it receives under this Agreement. If laws or regulations require that taxes be withheld, BMS shall: (a) deduct those taxes from the remittable payment; (b) pay the taxes to the proper taxing authority; and (c) send evidence of the obligation together with proof of tax payment to Exelixis within [*] following that tax payment. The Parties shall discuss appropriate mechanisms for minimizing such taxes to the extent possible in compliance with applicable law.

7.11 Blocked Currency. In each country where the local currency is blocked and cannot be removed from the country, royalties accrued in that country shall be paid to Exelixis in Dollars based on the Dollar reported sales for the quarter (translated for such country per Statement of Financial Standards No. 52), unless otherwise mutually agreed.

7.12 Sublicenses. In the event BMS grants any permitted licenses or sublicenses to Third Parties to sell Products that are subject to royalty payments under Section 7.3, BMS shall have the responsibility to account for and report sales of any Product by a licensee or a sublicensee on the same basis as if such sales were Net Sales by BMS. BMS shall pay to Exelixis (or cause the licensee or sublicensee to pay to Exelixis, with BMS remaining responsible for any failure of the licensee or sublicensee to pay amounts when due under this Agreement): (a) royalties on such sales as if such sales of the licensee or sublicensee were Net Sales of BMS or any of its Affiliates; and (b) milestone payments pursuant to Section 7.2 based on the achievement by such licensee or sublicensee of any milestone event contemplated in such Sections as if such milestone event had

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been achieved by BMS or any of its Affiliates hereunder. Any sales by BMS’ Affiliates and sublicensees of BMS or such sublicensee’s Affiliates, in each case to Third Parties, shall be aggregated with sales by BMS for the purpose of calculating the aggregate Net Sales in Sections 7.2 and 7.3.

7.13 Foreign Exchange. Conversion of sales recorded in local currencies to Dollars shall be performed in a manner consistent with BMS’ normal practices used to prepare its audited financial statements for internal and external reporting purposes, which uses a widely accepted source of published exchange rates.

7.14 Records. BMS shall keep (and shall ensure that its Affiliates and sublicensees shall keep) such records as are required to determine, in a manner consistent with GAAP and this Agreement, the sums due under this Agreement, including Net Sales. All such books, records and accounts shall be retained by such Party until the later of (a) [*] after the end of the period to which such books, records and accounts pertain and (b) the [*] (or any extensions thereof), or for such longer period as may be required by applicable law. BMS shall require its sublicensees to provide to it a report detailing the foregoing expenses and calculations incurred or made by such sublicensee, which report shall be made available to Exelixis in connection with any audit conducted by Exelixis pursuant to Section 7.15.

7.15 Audits. Exelixis shall have the right to have an independent certified public accountant, reasonably acceptable to BMS, to have access during normal business hours, and upon reasonable prior written notice, to examine only those records of BMS (and its Affiliates and sublicensees) as may be reasonably necessary to determine, with respect to any calendar year ending not more than [*] prior to Exelixis’ request, the correctness or completeness of any report or payment made under this Agreement. The foregoing right of review may be exercised [*]. Results of any such examination shall be: (a) limited to information relating to the Products; (b) made available to both Parties; and (c) subject to Article 9. Exelixis shall bear the full cost of the performance of any such audit, unless such audit discloses a variance to the detriment of Exelixis of more than [*] from the amount of the original report, royalty or payment calculation, in which case BMS shall bear the full cost of the performance of such audit. The results of such audit shall be [*].

7.16 Interest. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) [*] Rate as published by Citibank, N.A., New York, New York, or any successor thereto, at 12:01 a.m. on the first day of each quarter in which such payments are overdue; or (b) the maximum rate permitted by law, in each case calculated on the number of days such payment is delinquent, compounded monthly.

7.17 Non-Monetary Consideration. In the event that BMS or its Affiliates or sublicensees receives any non-monetary consideration in connection with the sale of a Product, BMS’ payment obligations under this Article 7 shall be based on the fair market value of such consideration. In such case, BMS shall disclose the terms of such arrangement to Exelixis and the Parties shall endeavor in good faith to agree on such fair market value.

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7.18 Payments to or Reports by Affiliates. Any payment required under any provision of this Agreement to be made to either Party or any report required to be made by any Party shall be made to or by an Affiliate of that Party if designated in writing by that Party as the appropriate recipient or reporting entity.

8. EXCLUSIVITY

8.1 Licensed Compounds. This Agreement will be exclusive with respect to the Development, Manufacture, and Commercialization of [*] that are intended to [*], as described below.

(a) Prior to Commercialization. Subject to Sections 8.1(a)(i), 8.2, 8.3 and 8.4, [*], [*] (directly or indirectly, and either with or without a bona fide collaborator) outside the scope of this Agreement any programs: (I) that [*] that [*]; or (II) where [*].

(i) [*] of a Product. Upon either (A) the [*] of [*] Products pursuant to Section [*]; or (B) the [*] of [*] Product pursuant to Section [*]. [*] (directly or indirectly, and either with or without a bona fide collaborator) outside the scope of this Agreement programs to [*] that [directly bind and modulate such TGR5 without any further obligation to the other Party].

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(ii) [*] of [*]. In the event of any [*] of [*] that is permitted under Section [*], the Party [*] shall [*] a [*] of [*] of any [*] a [*] subsequent to [*] of [*] and [*] the [*] with respect to such [*] or [*] of this Agreement (in either case, [*]).

(b) Subsequent to Commercialization. Subject to Sections 8.2, 8.3 and 8.4, [*], [*] (directly or indirectly, and either with or without a bona fide collaborator) outside the scope of this Agreement any programs to [*] that [*], and any [*] subject to the following terms and conditions:

(i) Commercial Launch of [*]. (Neither Party may commercialize outside of the Agreement), any product [*]: (A) that is [*] and [*]; or (B) where the [*] that [such Small Molecule Compound directly binds and modulates TGR5 at the Target Potency Threshold] (any such product, a [*]), for a [*] of a [*].

8.2 [*]. Notwithstanding anything to the contrary set forth in this Article 8, if a Party is engaged in [*] a program that is [*] that is [*], and [*] such program [*], such Party shall [*] with such [*] in order to [*] so the [*] the [*] for [*].

8.3 Not Applicable to [*]. The restrictions and obligations in Section 8.1 shall not apply with respect to either Party for [*] that are [*] by such Party [*](either with or without a bona fide collaborator).

8.4 [*] Right. [*] may [*] with a [*] that [*] a [*] solely with respect to the [*] of [*] and/or a [*] that [*]: (a) any [*] product that is [*] a [*]; and (b) such [*] a [*], on the condition that [*] to [*] of [*] with respect to [*] as set forth herein (assuming such [*] and/or a [*]).

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

9. CONFIDENTIALITY

9.1 Nondisclosure of Confidential Information. All Information or Materials disclosed by one Party to the other Party pursuant to this Agreement, and, subject to Section 9.6, Information that is generated pursuant to this Agreement with respect to Licensed Compounds or Products (for so long as such Licensed Compound or Product is not removed from the Agreement as a result of a Product specific termination pursuant to Section 10.2 or Section 10.3), shall be “Confidential Information” for all purposes hereunder. The Parties agree that during the period from the Execution Date to the Effective Date, during term of this Agreement and for a period of [*] thereafter, a Party receiving Confidential Information of the other Party shall: (a) use Diligent Efforts to maintain in confidence such Confidential Information (but not less than those efforts as such Party uses to maintain in confidence its own proprietary industrial information of similar kind and value) and not to disclose such Confidential Information to any Third Party without prior written consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned), except for disclosures made in confidence to any Third Party under terms consistent with this Agreement and made in furtherance of this Agreement or of rights granted to a Party hereunder; and (b) not use such other Party’s Confidential Information for any purpose except those permitted by this Agreement (it being understood that this Section 9.1 shall not create or imply any rights or licenses not expressly granted under Article 6 or Article 10 hereof).

9.2 Exceptions. The obligations in Section 9.1 shall not apply with respect to any portion of the Confidential Information that the receiving Party can show by competent written proof:

(a) Is publicly disclosed by the disclosing Party, either before or after it is disclosed to the receiving Party hereunder; or

(b) Was known to the receiving Party or any of its Affiliates, without obligation to keep it confidential, prior to disclosure by the disclosing Party; or

(c) Is subsequently disclosed to the receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without obligation to keep it confidential; or

(d) Is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the receiving Party, and is not directly or indirectly supplied by the receiving Party in violation of this Agreement; or

(e) Has been independently developed by employees or contractors of the receiving Party or any of its Affiliates without the aid, application or use of the disclosing Party’s Confidential Information.

9.3 Authorized Disclosure. A Party may disclose the Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances; provided that notice of any such disclosure shall be provided as soon as practicable to the other Party:

(a) Filing or prosecuting Patents relating to Sole Inventions, Joint Inventions or Products, in each case pursuant to activities under this Agreement;
[⁎] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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(b) Regulatory filings;

c) Prosecuting or defending litigation;

d) Complying with applicable governmental laws and regulations; and

e) Disclosure, in connection with the performance of this Agreement, or exercise of its rights hereunder, to Affiliates, potential collaborators, partners, and actual and potential licensees (including potential co-marketing and co-promotion contractors, research contractors and manufacturing contractors), research collaborators, potential investment bankers, investors, lenders, and investors, employees, consultants, or agents, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9.

The Parties acknowledge that the terms of this Agreement shall be treated as Confidential Information of both Parties. Such terms may be disclosed by a Party to individuals or entities covered by Section 9.3(e) above, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9. In addition, a copy of this Agreement may be filed by either Party with the Securities and Exchange Commission in connection with any public offering of such Party’s securities, in connection with such Party’s on-going periodic reporting requirements under the federal securities laws, or as otherwise necessary under applicable law or regulations. In connection with any such filing, such Party shall endeavor to obtain confidential treatment of economic, competitively sensitive, and trade secret information.

9.4 Termination of Prior Agreements. All Information exchanged between the Parties under the Confidential Disclosure Agreement between Exelixis and BMS executed as of [⁎], and amended as of [⁎] and [⁎] (such confidential disclosure agreement, as amended, the “Prior CDA”) that relates to TGR5, Licensed Compounds or Products shall be deemed Confidential Information and shall, commencing upon the Execution Date, be subject to the terms of this Article 9 rather than the Prior CDA. The Prior CDA shall otherwise remain in full force and effect, including with respect to each Party’s rights with respect to breaches thereof, if any, that occurred prior to the Execution Date with respect to Information described in the first sentence of this Section 9.4.

9.5 Publicity. The Parties agree that the public announcement of the execution of this Agreement shall be substantially in the form of the press release attached as Exhibit 9.5. Any other publication, news release or other public announcement relating to this Agreement or to the performance hereunder, shall first be reviewed and approved by both Parties; provided, however, that any disclosure which is required by law, including disclosures required by the U.S. Securities and Exchange Commission or made pursuant to the requirements of the national securities exchange or other stock market on which such Party’s securities are traded, as advised by the disclosing Party’s counsel may be made without the prior consent of the other Party, although the other Party shall be given prompt notice of any such legally required disclosure and to the extent practicable shall provide the other Party an opportunity to comment on the proposed disclosure.

9.6 Publications. Subject to Section 9.3, each Party agrees to provide the other Party the opportunity to review any proposed disclosure which contains Confidential Information of the other Party and would or may constitute an oral, written or electronic public disclosure if made (including the full content of proposed abstracts, manuscripts or presentations), and which relate to any Inventions, at least [⁎] prior to its intended submission for publication and agrees, upon request, not to submit any such abstract or manuscript for publication until the other Party is given a reasonable period of time to secure patent protection for any material in such publication which it believes to be patentable; provided, however, that BMS may publish results of clinical studies relating to Licensed Compounds without the prior review or approval of Exelixis. Both Parties understand that a reasonable commercial strategy may require delay of publication of information or filing of patent applications. The Parties agree to review and consider delay of publication and filing of patent applications under certain circumstances. The Alliance Managers (or the Parties), as appropriate, shall review such requests and recommend subsequent action. Subject to Section 9.3, neither Party shall have the right to publish or present Confidential Information of the other Party which is subject to Section 9.1. Nothing contained in this Section 9.6 shall prohibit the inclusion of Confidential Information
Information of the non-filing Party necessary for a patent application, provided the non-filing Party is given a reasonable opportunity to review the extent and necessity for its Confidential Information to be included prior to submission of such patent application related to the Agreement. Any disputes between the Parties regarding delaying a publication or presentation to permit the filing of a patent application shall be referred to the Alliance Managers (or the Parties), as appropriate.

10. TERM AND TERMINATION

10.1 Term. This Agreement shall become effective on the Effective Date and shall remain in effect until terminated in accordance with Sections 10.2 or 10.3 or by mutual written agreement, or until the expiration of all payment obligations under Article 7 (the “Term”).

10.2 BMS’ Right to Terminate. BMS shall have the right to terminate this Agreement, at any time, on a Product-by-Product and country-by-country basis upon: (a) [*] prior written notice to Exelixis, in the event that such termination is [*] of the [*] or (b) [*] prior written notice to Exelixis, in the event that such termination is [*] of the [*].

10.3 Termination for Material Breach or Patent Challenge

(a) Notice. If either Party believes that the other is in material breach of this Agreement (including any material breach of a representation or warranty made in this Agreement), then the non-breaching Party may deliver notice of such breach to the other Party. In such notice the non-breaching Party shall identify the actions or conduct that such Party would consider to be an acceptable cure of such breach. For all breaches other than a failure to make a payment set forth in Article 7, the allegedly breaching Party shall have [*] to cure such breach. For any breach arising from a failure to make a payment set forth in Article 7, the allegedly breaching Party shall have [*] to cure such breach. (Note: [*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.)

(b) Cure Period. Subject to Section 10.3(c), if the Party receiving notice of breach fails to cure such breach within the [*] period or [*] period (as applicable), or the Party providing the notice reasonably determines that the proposed corrective plan or the actions being taken to carry it out is not commercially practicable, the Party originally delivering the notice may terminate this Agreement upon [*] advance written notice, provided, that if the breach [*] or [*], the non-breaching Party may [*] the [*] with respect to [*].

(c) [*] Material Breach. If a Party gives notice of termination under Section 10.3(a) and the other Party [*], or if a Party determines under Section 10.3(b) that the [*] or the [*] is [*] and such [*] such [*], then the [*]; (i) [*]; or (ii) [*] or the [*], shall in any case [*]. If [*] such [*] it is [*] the [*], then such termination shall [*] if the breaching Party fails [*] to cure such breach in accordance with the [*] within the time period set forth in Section 10.3(a) for the applicable breach [*]. If [*] such [*] it is [*] the [*], then [*] and [*].

(d) Termination for Patent Challenge. Exelixis may terminate this Agreement with respect to a given Product in a given country if BMS or its Affiliates or sublicensees, directly or indirectly, individually or in association with any other person or entity, challenge the validity, enforceability or scope of any Exelixis Licensed Patents that relate to such Product in such country; provided that, if BMS, due to a Change of Control transaction, acquires control of a company that is challenging, directly or indirectly, individually or in association with another person or entity, the validity, enforceability or scope of any Exelixis Licensed Patents, BMS shall have [*] from the date of such acquisition to terminate such challenge to such Exelixis Licensed Patents before Exelixis’ right to terminate under this Section 10.3(d) becomes effective. For clarity, any dispute as to whether a given Patent is within the scope of Exelixis Licensed Patents, such matter shall be subject to dispute resolution as set forth in Section 13.3.

10.4 Survival; Effect of Termination

(a) In the event of expiration or termination of this Agreement, the following provisions of this Agreement shall survive: Articles [*]; and Sections [*].

(b) In any event, expiration or termination of this Agreement shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party’s right to obtain performance of any obligation.

10.5 Licenses and Payments on Termination.
(a) Termination by BMS (Section 10.2). Subject to Section 10.5(e), if BMS terminates this Agreement pursuant to Section 10.2 with respect to a particular Product in any country, then the license granted to BMS under Section 6.1 shall automatically terminate solely with respect to such Product in such country, and BMS shall, and hereby does, grant to Exelixis a royalty-free license, with the right to grant sublicenses, under the BMS Licensed Patents and BMS Licensed Know-How to clinically develop, make, use, sell, offer for sale and import such Product in such country. The license described in this Section 10.5(a) shall be [*], except that it shall be [*] with respect to the [*].

(b) Termination by Exelixis (Section 10.3). If this Agreement terminates pursuant to Section 10.3 [*], and BMS is the breaching Party, then the license granted to BMS under Section 6.1 shall automatically terminate [*], and BMS shall, and hereby does, grant to Exelixis a license, with the right to grant sublicenses, under the BMS Licensed Patents and BMS Licensed Know-How to clinically develop, make, use, sell, offer for sale and import such Product [*]. The license described in this Section 10.5(b) shall be [*], except that it shall be [*] with respect to the [*]. For Products on which [*], the license described in this Section 10.5(b) shall be [*]. For Products on which [*] but which [*] and that are [*] of [*] or [*] in [*] that, in either case, [*] or the [*] or [*], the license described in this Section 10.5(b) shall bear a royalty of [*] of Exelixis' Net Sales of such Product. For Products on which [*] and that are [*] of [*] or [*] in [*] that, in either case, [*] or the [*] or [*], the license described in this Section 10.5(b) shall bear a royalty of [*] of Exelixis' Net Sales of such Product. Exelixis' right to receive royalties under this Section 10.5(b) shall expire on a country-by-country and Product-by-Product basis upon the later of: (i) [*]; or (ii) [*] or the [*].

(c) Termination by BMS (Section 10.3). If this Agreement terminates pursuant to Section 10.3 [*], and Exelixis is the breaching Party, then the license granted to BMS under Section 6.1, shall automatically terminate [*], and Exelixis shall, and hereby does, grant to BMS a license, with the right to grant sublicenses, under the Exelixis Licensed Patents and Exelixis Licensed Know-How to clinically develop, make, use, sell, offer for sale and import such Product [*]. The license described in this Section 10.5(c) shall be [*], except that it shall be [*] with respect to the [*]. For Products on which [*], the license described in this Section 10.5(c) shall [*]. For Products on which [*] but which [*] and that are [*] of [*] or [*] in [*] that, in either case, [*] or the [*] or [*], the license described in this Section 10.5(c) shall bear a royalty of [*] of Exelixis' Net Sales of such Product. For Products on which [*] and that [*] of [*] or [*] in [*] that, in either case, [*] or the [*] or [*], the license described in this Section 10.5(c) shall bear a royalty of [*] of BMS' Net Sales of such Product. For Products on which [*] and that [*] of [*] or [*] in [*] that, in either case, [*] or the [*] or [*], the license described in this Section 10.5(c) shall bear a royalty of [*] of BMS' Net Sales of such Product. Exelixis' right to receive royalties under this Section 10.5(c) shall expire on a country-by-country and Product-by-Product basis upon the later of: (i) [*]; or (ii) [*] or the [*].

(d) Transfers Related to Licenses. For each license granted under Sections 10.5(a) – 10.5(c), the licensing Party shall transfer via assignment, license or sublicense to the licensee Party: (i) all Information reasonably necessary for the development and commercialization of the Product to which such license relates; (ii) [*] that [*] relate to such Product and that are [*]; (iii) [*] that [*] relate to such Product; (iv) [*] Controlled by the licensing Party that [*] relate to such Product; and (v) supplies of such Product (including any intermediates, retained samples and reference standards), that, in each case (i) through (v) are existing and in the Control of the licensing Party. Any such transfer(s) shall be [*] of the [*].

(e) Exception for Termination for [*]. The license granted to [*] under Section [*] shall be [*] with respect to any given Product where [*] termination of Development and/or Commercialization of such Product was due to [*]. For purposes of this Section 10.5(e), [*] means it is [*] or [*] that there is [*] for [*]: (i) [*], including [*]; or (ii) the [*] of [*] a Product [*] or [*], such as [*] or [*] a Product. Notwithstanding anything to the contrary, this Section 10.5(e) shall not prevent [*] from using its license in Section [*] to [*] by [*] that was [*]. [*] shall provide [*] with all [*] for such [*] but shall not [*] to [*] any [*] relating to such [*].

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may be necessary to effect the transfer of rights hereunder to Exelixis.

(ii) Breach Transfer. In the event of any termination pursuant to Section 10.3, the breaching Party shall transfer and assign to the non-breaching Party: (i) all Information relating to the Product, and [* ] with respect to Product in the breaching Party’s name; (ii) all [* ] related to the Product, to the extent that [* ]; (iii) all [* ] related to the Product; and (iv) all supplies of Product (including any intermediates, retained samples and reference standards) that in each case are in the breaching Party’s Control and that relate to the Product. The breaching Party shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to the non-breaching Party.

10.6 Interim Supply. In the event of any termination of a Product pursuant to Section 10.2, or Section 10.3 (where BMS is the breaching Party), in each case [* ] at Exelixis’ written request, BMS shall supply, or cause to be supplied, to Exelixis sufficient quantities of Product to satisfy Exelixis’ requirements for Product for a period of up to [* ] following the effective date of termination, as Exelixis may require until Exelixis can itself assume or transition to a Third Party such manufacturing responsibilities; provided, however that Exelixis shall use Diligent Efforts to affect such assumption (or transition) as promptly as practicable. Such supply shall be [* ] with respect to development supply, and shall be [* ] for such Product(s) with respect to commercial supply. Any such supply will be made pursuant to a supply agreement between the Parties with typical provisions relating to quality, forecasting and ordering to forecast, force majeure and product liability and indemnity. In the event that BMS has one or more agreements with Third Party manufacturers with respect to the manufacture of a Product, at Exelixis’ request, BMS shall use commercially reasonable efforts to transfer its rights and obligations under such agreement(s) to Exelixis upon any such termination.

11. REPRESENTATIONS AND WARRANTIES AND COVENANTS

11.1 Mutual Authority. Exelixis and BMS each represents and warrants to the other as of the Execution Date that: (a) it has the authority and right to enter into and perform this Agreement, (b) this Agreement is a legal and valid obligation binding upon it and is enforceable in accordance with its terms, subject to applicable limitations on such enforcement based on bankruptcy laws and other debtors’ rights, and (c) its execution, delivery and performance of this Agreement shall not conflict in any material fashion with the terms of any other agreement or instrument to which it is or becomes a party or by which it is or becomes bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having authority over it.

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Affiliates to comply with the provisions of this Agreement in connection with such performance. In particular, if any Affiliate of a Party participates under this Agreement with respect to Licensed Compounds: (a) the restrictions of this Agreement which apply to the activities of a Party with respect to Licensed Compounds shall apply equally to the activities of such Affiliate; and (b) the Party affiliated with such Affiliate shall assure, and hereby guarantees, that any intellectual property developed by such Affiliate shall be governed by the provisions of this Agreement (and subject to the licenses set forth in Article 6) as if such intellectual property had been developed by the Party.

11.4 Third Party Rights. Each Party represents and warrants to the other Party that, to its Knowledge as of the Execution Date, its performance of work as contemplated by this Agreement shall not infringe the valid patent, trade secret or other intellectual property rights of any

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Third Party. Each Party represents and warrants to the other Party that, to its Knowledge as of the Execution Date, it will not violate a contractual or fiduciary obligation owed to such Third Party (including misappropriation of trade secrets) by performing its work as contemplated by this Agreement.

11.5 Notice of Infringement or Misappropriation. Each Party represents and warrants to the other Party that, as of the Execution Date, it has received no notice of infringement or misappropriation of any alleged rights asserted by any Third Party in relation to any technology that such Party intends, as of the Execution Date, to use in connection with the Agreement.

11.6 HSR Act Filing; Effective Date. The Parties shall each, prior to or as promptly as practicable after the Execution Date of this Agreement, file or cause to be filed with the U.S. Federal Trade Commission and the U.S. Department of Justice and any relevant foreign governmental authority any notifications required to be filed under the HSR Act and any applicable foreign equivalent thereof with respect to the transactions contemplated hereby; provided that the Parties shall each file the notifications required to be filed under the HSR Act no later than [*] after the Execution Date of this Agreement. Each Party shall be responsible for its own costs in connection with such filing, except that BMS shall be [*]. The Parties shall use commercially reasonable efforts to respond promptly to any requests for additional information made by either of such agencies, and to cause the waiting periods under the HSR Act and any applicable foreign equivalent thereof to terminate or expire at the earliest possible date after the date of filing. Each Party shall use its commercially reasonable efforts to ensure that its representations and warranties set forth in this Agreement remain true and correct at and as of the Effective Date as if such representations and warranties were made at and as of the Effective Date. Notwithstanding anything in this Agreement to the contrary, this Agreement (other than Article 9 and this Section 11.6) [*] under the HSR Act in the U.S., the expiration or earlier termination of any applicable waiting period under the antitrust or competition laws of any other jurisdiction, and the approval or clearance of the transactions contemplated by this Agreement in any jurisdiction requiring advance approval or clearance (the "Effective Date").

12. INDEMNIFICATION AND LIMITATION OF LIABILITY

12.1 Mutual Indemnification. Subject to Section 12.3, each Party hereby agrees to indemnify, defend and hold harmless the other Party, its Affiliates, and their respective directors, employees and agents from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses and/or losses, including reasonable legal expenses and reasonable attorneys' fees ("Losses") to the extent such Losses result from any: (a) breach of warranty by the indemnifying Party contained in the Agreement; (b) breach of the Agreement or applicable law by such indemnifying Party; (c) negligence or willful misconduct of the indemnifying Party, its Affiliates or (sub)licensees, or their respective directors, employees and agents in the performance of the Agreement; and/or (d) breach of a contractual or fiduciary obligation owed by it to a Third Party (including misappropriation of trade secrets).

12.2 Indemnification.

(a) Indemnification by BMS. Subject to Section 12.3, BMS hereby agrees to indemnify, defend and hold harmless Exelixis and its directors, employees and agents from and
against any and all Losses to the extent such Losses result from [*] or [*] by BMS or its Affiliates, agents or sublicensees, except to the extent such Losses result from any: (a) breach of warranty by Exelixis contained in the Agreement; (b) breach of the Agreement or applicable law by Exelixis; (c) negligence or willful misconduct by Exelixis, its Affiliates or (sub)licensees, or their respective directors, employees and agents in the performance of the Agreement; and/or (d) breach of a contractual or fiduciary obligation owed by Exelixis to a Third Party (including misappropriation of trade secrets).

(b) Indemnification by Exelixis. Subject to Section 12.3, Exelixis hereby agrees to indemnify, defend and hold harmless BMS and its directors, employees and agents from and against any and all Losses to the extent such Losses result from [*] or [*] by Exelixis or its Affiliates, agents or sublicensees, except to the extent such Losses result from any: (a) breach of warranty by BMS contained in the Agreement; (b) breach of the Agreement or applicable law by BMS; (c) negligence or willful misconduct by BMS, its Affiliates or (sub)licensees, or their respective directors, employees and agents in the performance of the Agreement; and/or (d) breach of a contractual or fiduciary obligation owed by BMS to a Third Party (including misappropriation of trade secrets).

12.3 Conditions to Indemnification. As used herein, "Indemnitee" shall mean a party entitled to indemnification under the terms of Sections 12.1 or 12.2. A condition precedent to each Indemnitee’s right to seek indemnification under such Sections 12.1 or 12.2 is that such Indemnitee shall:

(a) inform the indemnifying Party under such applicable Section of a Loss as soon as reasonably practicable after it receives notice of the Loss;

(b) if the indemnifying Party acknowledges that such Loss falls within the scope of its indemnification obligations hereunder, permit the indemnifying Party to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Loss (including the right to settle the claim solely for monetary consideration); provided, that the indemnifying Party shall seek the prior written consent (such consent not to be unreasonably withheld, delayed or conditioned) of any such Indemnitee as to any settlement which would materially diminish or materially adversely affect the scope, exclusivity or duration of any Patents licensed under this Agreement, would require any payment by such Indemnitee, would require an admission of legal wrongdoing in any way on the part of an Indemnitee, or would effect an amendment of this Agreement; and

(c) fully cooperate (including providing access to and copies of pertinent records and making available for testimony relevant individuals subject to its control) as reasonably requested by, and at the expense of, the indemnifying Party in the defense of the Loss.

Provided that an Indemnitee has complied with all of the conditions described in subsections 12.3(a) – (c), as applicable, the indemnifying Party shall provide attorneys reasonably acceptable to the Indemnitee to defend against any such Loss. Subject to the foregoing, an Indemnitee may participate in any proceedings involving such Loss using attorneys of the Indemnitee’s choice and at the Indemnitee’s expense. In no event may an Indemnitee settle or compromise any Loss for which the Indemnitee intends to seek indemnification from the indemnifying Party hereunder

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WITH RESPECT TO ANY COMPOUNDS, MATERIALS OR INFORMATION (AND ANY PATENT RIGHTS OBTAINED THEREON) IDENTIFIED, MADE OR GENERATED BY EXELIXIS AS PART OF THE COLLABORATION OR OTHERWISE MADE AVAILABLE TO BMS PURSUANT TO THE TERMS OF THE AGREEMENT.

13. MISCELLANEOUS

13.1 Dispute Resolution. Unless otherwise set forth in this Agreement and excluding in particular any dispute described in Section 13.3 (which will be handled exclusively in accordance with Section 13.3), in the event of any dispute, controversy or claim arising out of, relating to or in connection with any provision of the Agreement, the Parties shall try to settle their differences amicably between themselves first, by referring the disputed matter to the Party’s respective Executive Officers. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and, within [*] after such notice, such Executive Officers shall meet for attempted resolution by good faith negotiations. If such Executive Officers are unable to resolve such dispute within [*] of their first meeting for such negotiations, either Party may seek to have such dispute resolved in any U.S. federal or state court of competent jurisdiction and appropriate venue, provided, that if such suit includes a Third Party claimant or defendant, and jurisdiction and venue with respect to such Third Party appropriately resides outside the U.S., then in any other jurisdiction or venue permitted by applicable law.

13.2 Governing Law. Resolution of all disputes, controversies or claims arising out of, relating to or in connection with the Agreement or the performance, enforcement, breach or termination of the Agreement and any remedies relating thereto, shall be governed by and construed under the substantive laws of the State of Delaware, without regard to conflicts of law rules.

13.3 Patents and Trademarks; Equitable Relief.

(a) Except as set forth in Section 6.7(a)(i), any dispute, controversy or claim arising out of, relating to or in connection with: (i) the scope, validity, enforceability or infringement of any Patent rights covering the research, development, manufacture, use or sale of any Product; or (ii) any trademark rights related to any Product, shall in each case be submitted to a court of competent jurisdiction in the territory in which such Patent or trademark rights were granted or arose.

(b) Any dispute, controversy or claim arising out of, relating to or in connection with the need to seek preliminary or injunctive measures or other equitable relief (e.g., in the event of a potential or actual breach of the confidentiality and non-use provisions in Article 9) need not be resolved through the procedure described in Section 13.1 but may be immediately brought in a court of competent jurisdiction.

13.4 Entire Agreement; Amendments. This Agreement, the collaboration agreement (for the discovery, development and commercialization of compounds that antagonize the target known as ROR) that is between Exelixis and BMS and that is dated as of the Execution Date (the “ROR Collaboration Agreement”), and the letter agreement that is dated as of the Execution Date and that describes Exelixis' creation of a licensing Affiliate (the “Letter Agreement”), set forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement, the ROR Collaboration Agreement, and the Letter Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

13.5 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the U.S. or other countries which may be imposed upon or related to Exelixis or BMS from time to time. Each Party agrees that it shall not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of

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export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity.

13.6 Bankruptcy.

(a) All rights and licenses granted under or pursuant to this Agreement, including amendments hereto, by each Party to the other Party are, for all purposes of Section 365(n) of Title 11 of the U.S. Code ("Title 11"), licenses of rights to intellectual property as defined in Title 11. Each Party agrees during the term of this Agreement to create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property. If a case is commenced by or against either Party (the "Bankrupt Party") under Title 11, then, unless and until this Agreement is rejected as provided in Title 11, the Bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 Trustee) shall, at the election of the Bankrupt Party made within sixty (60) days after the commencement of the case (or, if no such election is made, immediately upon the request of the non-Bankrupt Party) either (i) perform all of the obligations provided in this Agreement to be performed by the Bankrupt Party including, where applicable, providing to the non-Bankrupt Party portions of such intellectual property (including embodiments thereof) held by the Bankrupt Party and such successors and assigns or otherwise available to them or (ii) provide to the non-Bankrupt Party all such intellectual property (including all embodiments thereof) held by the Bankrupt Party and such successors and assigns or otherwise available to them.

(b) If a Title 11 case is commenced by or against the Bankrupt Party and this Agreement is rejected as provided in Title 11 and the non-Bankrupt Party elects to retain its rights hereunder as provided in Title 11, then the Bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 Trustee) shall provide to the non-Bankrupt Party all such intellectual property (including all embodiments thereof) held by the Bankrupt Party and such successors and assigns or otherwise available to them immediately upon the Bankrupt Party’s written request therefor. Whenever the Bankrupt Party or any of its successors or assigns provides to the non-Bankrupt Party any of the intellectual property licensed hereunder (or any embodiment thereof) pursuant to this Section 13.6, the non-Bankrupt Party shall have the right to perform the obligations of the Bankrupt Party hereunder with respect to such intellectual property, but neither such provision nor such performance by the non-Bankrupt Party shall release the Bankrupt Party from any such obligation or liability for failing to perform it.

(c) All rights, powers and remedies of the non-Bankrupt Party provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including Title 11) in the event of the commencement of a Title 11 case by or against the Bankrupt Party. The non-Bankrupt Party, in addition to the rights, power and remedies expressly provided herein, shall be entitled to exercise all other such rights and powers and resort to all other such remedies as may now or hereafter exist at law or in equity (including under Title 11) in such event. The Parties agree that they intend the foregoing non-Bankrupt Party rights to extend to the maximum extent permitted by law and any provisions of applicable contracts with Third Parties, including for purposes of Title 11, (i) the right of access to any intellectual property (including all embodiments thereof) of the Bankrupt Party or any Third Party with whom the Bankrupt Party contracts to perform an obligation of the Bankrupt Party under this Agreement, and, in the case of the Third Party, which is necessary for the development, registration and manufacture of Products and (ii) the right to contract directly with any Third Party described in (i) in this sentence to complete the contracted work. Any intellectual property provided pursuant to the provisions of this Section 13.6 shall be subject to the licenses set forth elsewhere in this Agreement and the payment obligations of this Agreement, which shall be deemed to be royalties for purposes of Title 11.

13.7 Force Majeure. Each Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (defined below) and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, “force majeure” shall include conditions beyond the control of the Parties, including an act of God, acts of terrorism, voluntary or involuntary compliance with any regulation, law or order of any government, war, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. The payment of invoices due and owing hereunder shall in no event be delayed by the payer because of a force majeure affecting the payer.

13.8 Notices. Any notices given under this Agreement shall be in writing, addressed to the Parties at the following addresses, and delivered by person, by facsimile (with receipt confirmation), or by FedEx or other reputable courier service. Any such notice shall be deemed to have been given: (a) as of the day of personal delivery; (b) one (1) day after the date sent by facsimile service; or (c) on the day of successful delivery to the other Party confirmed by the courier service. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

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For Exelixis: Exelixis, Inc.
170 Harbor Way
P.O. Box 511
So. San Francisco, CA 94083-0511
Attention: EVP, General Counsel
With a copy to: Cooley LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306
Attention: Marya A. Postner, Esq.
For BMS: Bristol-Myers Squibb Company
P.O. Box 4000
Route 206 and Province Line Road
Princeton, NJ 08543-4000
Attention: Senior Vice President, Strategy, Transactions and Alliances
Phone: 609-252-5333
Fax: 609-252-7212

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With a copy to: Bristol-Myers Squibb Company
P.O. Box 4000
Route 206 and Province Line Road
Princeton, NJ 08543-4000
Attention: Vice President and Asst. General Counsel, Business Development
Phone: 609-252-5328
Fax: 609-252-4232

Furthermore, a copy of any notices required or given under Article 6 of this Agreement shall also be addressed to the [*] of [*] at the address set forth in Section 6.8(f).

13.9 Maintenance of Records Required by Law or Regulation. Each Party shall keep and maintain all records required by law or regulation with respect to Products and shall make copies of such records available to the other Party upon request.
13.10 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other (such consent not to be unreasonably withheld, delayed or conditioned), except a Party may make such an assignment without the other Party’s consent to an Affiliate or to a Third Party successor to all or substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction; provided that any such permitted successor or assignee of rights and/or obligations hereunder is obligated, by reason of operation of law or pursuant to a written agreement with the other Party, to assume performance of this Agreement or such rights and/or obligations; and provided, further, that if assigned to an Affiliate, the assigning Party shall remain jointly and severally responsible for the performance of this Agreement by such Affiliate. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 13.10 shall be null and void and of no legal effect.

13.11 Electronic Data Interchange. If both Parties elect to facilitate business activities hereunder by electronically sending and receiving data in agreed formats (also referred to as Electronic Data Interchange or “EDI”) in substitution for conventional paper-based documents, the terms and conditions of this Agreement shall apply to such EDI activities.

13.12 Non-Solicitation of Employees. [ * ], each Party agrees that neither it nor any of its divisions, operating groups or Affiliates shall recruit, solicit or induce any employee of the other Party directly involved in the activities conducted pursuant to this Agreement to terminate his or her employment with such other Party and become employed by or consult for such Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing, “recruit”, “solicit” or “induce” shall not be deemed to mean: (a) circumstances where an employee of a Party initiates contact with the other Party or any of its Affiliates with regard to possible employment; or (b) general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements.

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13.13 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

13.14 Severability. If any of the provisions of this Agreement are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

13.15 No Waiver. Any delay in enforcing a Party’s rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party’s rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular period of time.

13.16 Construction of this Agreement. Except where the context otherwise requires, wherever used, the use of any gender shall be applicable to all genders, and the word “or” are used in the inclusive sense. When used in this Agreement, “including” means “including without limitation”. References to either Party include the successors and permitted assigns of that Party. The headings of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The Parties have each consulted counsel of their choice regarding this Agreement, and, accordingly, no provisions of this Agreement shall be construed against either Party on the basis that the Party drafted this Agreement or any provision thereof. If the terms of this Agreement conflict with the terms of any Exhibit, then the terms of this Agreement shall govern. The official text of this Agreement and any Exhibits hereto, any notice given or accounts or statements required by this Agreement, and any dispute proceeding related to or arising hereunder, shall be in English. In the event of any dispute concerning the construction or meaning of this Agreement, reference shall be made only to this Agreement as written in English and not to any other translation into any other language.

13.17 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be an original and all of which shall constitute together the same document. Counterparts may be signed and delivered by facsimile, or electronically in PDF format, each of which shall be binding when sent.

Signature page follows.

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IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their proper officers. The date that this Agreement is signed shall not be construed to imply that the document was made effective on that date.

BRISTOL-MYERS SQUIBB COMPANY EXELIXIS, INC.

By:
/s/ Jeremy Levin

By:
/s/ Michael Morrissey

Title:
Senior Vice President

Title:
CEO

Date:
10/08/2010

Date:
10/08/2010

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Exhibit 1.17
List of Exelixis Licensed Patents

Exelixis Ref. No.

External

Counsel

(*EC*) EC Ref. No. Country App. No. Title

[*]

[*][*][*][*][*]

[*]

[*][*][*][*][*]

[*]
Exhibit 2.2

Form of Transfer Addendum

This Transfer Addendum No.         (the “Transfer Addendum”) to the license agreement between Bristol-Myers Squibb Company and Exelixis, Inc., effective as of             , 2010 (the “License Agreement”), is made as of                     {Note: Please insert date} (the “Addendum Effective Date”), by and between:

Transferring Party: Exelixis, Inc.

And

Receiving Party: Bristol-Myers Squibb Company

for the transfer of:
(1) Information:

(Note: Please identify any Information other than the Materials that would be transferred, e.g., assay protocols, or else add “N/A” if not applicable.)

(2) Materials:

(i) the following biological materials:

(Note: Please identify any cell-lines, reagents, genes, vectors and constructs that would be transferred, or else add “N/A” if not applicable.)

(ii) the following [Licensed Compounds] known as:

(Note: Please insert identifier of the applicable compounds, or else add “N/A” if not applicable.)

Terms and Special Terms

The Parties agree that the transfer of the above defined Information and Materials pursuant to this Transfer Addendum shall be covered and submitted to the terms and conditions of the License Agreement. Any special terms and conditions identified on Appendix A, attached hereto and incorporated herein, shall also apply to the transfer of the Materials under this Transfer Addendum.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

IN WITNESS WHEREOF, this Transfer Addendum is entered into as of the Addendum Effective Date, and it is accepted and agreed to by the Parties’ authorized representatives. The date that this Transfer Addendum is signed shall not be construed to imply that the document was made effective on that date.

Name: (Note: insert name of AM) Name: (Note: insert name of AM)

For Exelixis For BMS

Title: Alliance Manager

Title: Alliance Manager

Date:

Date:

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.
Appendix A to Transfer Addendum

Special Terms

The following special terms and conditions apply to the transfer of the Materials under this Transfer Addendum.

(Note: Please identify any special terms and conditions, or else add “N/A” if not applicable.)

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Exhibit 9.5

Press Release

Contact:
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Vice President
Corporate Communications & Investor Relations
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EXELIXIS LICENSES PROGRAMS TO BRISTOL-MYERS SQUIBB COMPANY

-Exelixis to receive initial payment of $60 million-

SOUTH SAN FRANCISCO, Calif., October XX, 2010 — Exelixis, Inc. (NASDAQ: EXEL) announced today that it has entered into two new collaboration agreements with Bristol-Myers Squibb Company (NYSE:BMY). Under the first agreement, Exelixis will grant to Bristol-Myers Squibb an exclusive license to its small-molecule TGR5 agonist program including backups. Under the second agreement, the companies will collaborate to discover, optimize, and characterize small-molecule ROR antagonists. The companies have also made minor amendments to their XL281 and liver X receptor (LXR) agreements. Finally, under the companies’ cancer collaboration agreement Exelixis has opted to exercise its right to opt out of further co-development of XL139 and will receive an accelerated milestone payment.

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Under the terms of the new agreements, Bristol-Myers Squibb will make a combined initial payment of $60 million to Exelixis. Exelixis will be eligible for potential development and approval milestone payments of up to $250 million on TGR5 and $255 million on the ROR antagonists. Exelixis will also be eligible for combined sales performance milestones, and royalties on net sales of products from each of the TGR5 and ROR programs. Bristol-Myers Squibb will receive an exclusive worldwide license to develop and commercialize small molecule TGR5 agonists and ROR antagonists. Under the TGR5 agreement, Bristol-Myers Squibb will have sole responsibility for research, development, manufacturing, and commercialization. Under the ROR agreement, Bristol-Myers Squibb and Exelixis will collaborate on ROR antagonist programs up to a pre-clinical transition point and then Bristol-Myers Squibb will have sole responsibility for the further research, development, manufacture, and commercialization.

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Exelixis is granting rights to the ROR program in exchange for Bristol-Myers Squibb waiving rights to receive a third Investigational New Drug (IND) candidate as agreed to under a collaboration signed in 2006 between the two companies in the area of oncology.

After Exelixis opts-out of further co-development of XL139, Bristol-Myers Squibb will receive an exclusive worldwide license to develop and commercialize, and will have sole responsibility for the further development, manufacture, and commercialization of the compound.

“We continue our strong relationship with Bristol-Myers Squibb and are excited for these collaborations to maximize the potential of these novel programs and bring benefits to patients with serious diseases,” said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. “These transactions leverage our discovery expertise with the development expertise of Bristol-Myers Squibb in inflammation and metabolic diseases, and provide important additional resources for us to continue our focus on our clinical stage development pipeline.”

TGR5 is a G-protein coupled bile acid receptor (GPCR) which is highly expressed in the gall bladder and intestine. Through TGR5, bile acids promote the secretion of glucagon-like peptide-1 (GLP-1), a hormone that affects multiple metabolic parameters including increased insulin secretion from the pancreas and lowering of blood glucose. Stimulating GLP-1 secretion by activation of TGR5 has the potential to be complementary to the use of dipeptidyl peptidase-4 (DPP-IV) inhibitors for the treatment of diabetes.

ROR is a member of the nuclear hormone receptor family that is expressed in multiple cell types including T-cells. ROR plays a prominent role in the development and activity of the TH17 subset of T-cells, which secrete IL-17 and are associated with a variety of inflammatory disorders. Small molecule antagonists of ROR inhibit production of these pro-inflammatory cytokines and have broad potential as novel anti-inflammatory compounds.

The TGR5 license agreement and the amendment to the 2007 cancer collaboration agreement are subject to antitrust clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary regulatory approvals.

About Exelixis

Exelixis, Inc. is a development-stage biotechnology company dedicated to the discovery and development of novel small molecule therapeutics for the treatment of cancer and other serious diseases. The company is leveraging its biological expertise and integrated research and development capabilities to generate a pipeline of development compounds with significant therapeutic and commercial potential for the treatment of cancer and potentially other serious diseases. Currently, Exelixis’ broad product pipeline includes investigational compounds in phase 3, phase 2, and phase 1 clinical development. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, sanofi-aventis, GlaxoSmithKline, Genentech (a wholly owned member of the Roche Group), Boehringer Ingelheim, and Daiichi-Sankyo. For more information, please visit the company’s web site at http://www.exelixis.com.

Exelixis and the Exelixis logo are registered U.S. trademarks.

[Insert Forward-Looking Statements]

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